Guidelines on the Review of Over-The-Counter (OTC) Drug

(OTC Monograph)

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Anti-allergic drug products

A. Scope

This guideline applies to oral products for the temporary relief of symptoms caused by allergic rhinitis, hayfever and allergy.

Anti-allergic preparations mentioned in this guideline refers to the products of following conditions:

I. For the temporary relief of symptoms (nasal congestion, runny nose, sneezing, itchy eye and throat) caused by allergic rhinitis, hayfever, or itching and prurigo resulting from allergy.
II. Oral adminstration.

B. Active ingredients

Ⅰ. Active ingredient and dose:

1. The active ingredients specified in Table 1 are applicable to this guideline.
2. Table 1 stipulates the maximum single dose and the maximum daily dose of each active ingredient in category A, B and C.
3. Table 1 stipulates the upper and lower limit of the daily dose for each active ingredient in category D.

Table 1. Active ingredient and dose

Category	Group	Active ingredients	Maxiumum single dose (mg)	Maximum daily dose (mg)
A		Brompheniramine maleate	4	16
		Carbinoxamine maleate	4	16
		Chlorcyclizine hydrochloride	25	75
		Chlorpheniramine maleate (dl-Chlorpheniramine maleate)	4	16

Table 1. Types of active ingredients (continued)

Category	Group	Active ingredients		Maximum single dose (mg)	Maximum daily dose (mg)
A		Clemastine (fumarate)		1(Base)	2(Base)
		Dexbrompheniramine maleate		2	8
		Dexchlorpheniramine maleate (d-Chlorpheniramine maleate)		2	8
		Diphenhydramine hydrochloride		25-50	150
		Diphenhydramine salicylate		25	75
		Diphenylpyraline hydrochloride		4	12
		Isothipendyl hydrochloride		4	16
		Phenindamine tartrate		25	100
		Pheniramine maleate		25	100
		Pyrilamine maleate		25	100
		Triprolidine hydrochloride		2.5	10
B		dl-Methylephedrine hydrochloride		20	60
		Phenylephrine hydrochloride		10	40
		Pseudoephedrine hydrochloride		60	240
		Pseudoephedrine sulfate		60	240
C		Caffeine		50	150
		Caffeine anhydrous		50	150
Category	Group	Type		daily dose (mg)	
D	1	Vitamin B_2		2-12	
		Active ingredients	Riboflavin (Vitamin B_2) Riboflavin butyrate Riboflavin sodium phosphate		
	2	Vitamin B_6		5-50	
		Active ingredients	Pyridoxine hydrochloride		
	3	Biotin		0.01-0.50	
	4	Calcium pantothenate		5-30	
	5	Niacinamide (Nicotinamide)		12-60	
	6	Orotic acid		60-200	

Ⅱ. Combination rules (see Table 2):

1. Rhinitis medication:

(1)Essential composing ingredients: The active ingredients in category A and B of Table 1. The formula must contain one ingredient in category A and one ingredient in category B.

(2)Optional composing ingredients: The active ingredients in category C of Table 1, which can be used at most one in combination with essential composing ingredient.

2. Anti-allergic medication:

(1) Essential composing ingredients: The active ingredients in category A of Table 1. The formula must contain one ingredient in category A.

(2) Optional composing ingredients: The active ingredients in category D of Table 1, which can be used in combination with the essential composing ingredient. However, a formulation basis adopted in one of the ten advanced countries should be submitted when an active ingredient in category D is used.

3. Clemastine (fumarate) in category A of Table 1 is limited to single-ingredient preparation only.

III. Combination dose of active ingredients (see Table 2):

1. In Table 1, one-time dose of active ingredient must not exceed the maximum single dose specified in Table 1.
2. The one-time dose of diphenhydramine hydrochloride in category A of Table 1 shall follow the upper and lower limits of the maximum single dose stipulated in Table 1.
3. The combination coefficient of the ingredients in category A of Table 1 should be between 1 and 1/2. In other words, the ratio of the daily

dose to the maximum daily dose of the ingredient in category A should be between 1 and 1/2.

4. When the formula contains an ingredient in category B or C of Table 1, the combination coefficient for each category should be between 1 and 1/5. In other words, the ratio of daily dose to the maximum daily dose of the ingredient in category B (or C) should be between 1 and 1/5.
5. When the formula contains ingredient(s) in category D of Table 1:
   (1) The daily dose of each ingredient in category D shall follow the upper and lower limits stipulated in Table 1.
   (2) When two or more ingredients in group 1 of category D were combined, the combination coefficient cannot be greater than 1. In other words, the sum of the ratio of daily dose to the maximum daily dose of each ingredient shall not exceed 1.

Table 2　Combination rules and coefficient

Active ingredients \ Preparations		Combination rules		Combination coefficient		Notes
		Rhinitis medication	anti-allergic medication	Combined with one ingredient in the same category	Combined with at least two ingredients in the same Group	
Category A	Antihistamine	◎	◎	1/2≦　≦1		1.Should be combined with one ingredient; 2.Clemastine (fumarate) is limited to single-ingredient preparation only
Category B	Sympathomimetic	◎	×	1/5≦　≦1		Rhinitis medication should be compounded with one ingredient

Category C	Caffeine type		○	×	1/5≦ ≦1		Can be combined with at most one ingredient.
Category D	Group 1	Vitamin B_2	×	○	Based on Table 1	≦1	From Table 1: Based on the upper and lower limits of daily dose stipulated in Table 1.
	Group 2	Vitamin B_6	×	○	Based on Table 1		
	Group 3	Biotin	×	○	Based on Table 1		
	Group 4	Calcium pantothenate	×	○	Based on Table 1		
	Group 5	Niacinamide	×	○	Based on Table 1		
	Group 6	Orotic acid	×	○	Based on Table 1		

◎: Essential composing ingredient ○ : Optional composing ingredient ×: non-composing ingredient..

C. Dosage form

Limited to tablets, film coated tablets, sugar coated tablets, soft capsules, oral solutions, syrups, powders, powders for solution, powders for syrup, granules for internal use, granules for syrup, and fine granules..

D. Use (indications)

Indications vary depending on essential composing ingredients.

Preparations	Essential composing ingredients (◎)	Indication(s)
Rhinitis medication	Category A and B	To relieve symptoms (nasal congestion, runny nose, sneezing, eye and throat itching) caused by allergic rhinitis and hay fever.

Anti-allergic medication	Category A	To relieve symptoms (runny nose, sneezing, eye and throat itching) caused by allergic rhinitis and hay fever, itching and prurigo resulting from allergies.

E. Precautions

I. Do not use in the following conditions:

1. People who are allergic to the ingredient(s) of this product.
2. Breastfeeding women

   (Must be indicated for preparations containing diphenhydramine hydrochloride or diphenhydramine salicylate.)
3. Those who are taking or have taken monoamine oxidase inhibitors (MAOI) in the past 2 weeks. If you do not know whether the drugs you are taking contain MAOI, please consult your doctor or pharmacist.

   (Must be indicated for preparations containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, or pseudoephedrine sulfate.)

Ⅱ.Under the following conditions, consult your doctor before use:

1. Children under the age of 3 years.
2. Children under the age of 12 years.

   (Must be indicated for preparations containing clemastine (fumarate) or caffeine in category C.)
3. Children under the age of 6 years.

   (Must be indicated for preparations containing triprolidine hydrochloride.)
4. People with severe metabolic liver or kidney disease..

5. You have a history of the following diseases: Heart disease, hypertension, diabetes, hyperthyroidism, or difficulty in urination due to prostatic hyperplasia.
   (Must be indicated for preparations containing ingredients in category B.)
6. You have a history of respiratory disease, such as chronic bronchitis, emphysema, chronic lung disease, shortness of breath, or difficulty breathing, and people with glaucoma or [people with difficulty in urination due to prostatic hyperplasia]..
   (Must be indicated for preparations containing ingredients in category A.) If the words in brackets ([ ]) are indicated in the preceding item, they need not be repeated.
7. People with heart disease or adults aged 65 years and over.
   (Must be indicated for preparations containing dl-methylephedrine hydrochloride.)

Ⅲ.Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

1. pregnant women, women who might be pregnant, and breastfeeding women.
   (However, if "1. Do not use in the following situations" is indicated, breastfeeding women shall be omitted.
2. Adults aged 65 years and over.
3. People who are taking sedatives or sleeping medicines.
4. People who are taking other common cold medicines, antitussive or expectorant medicines, antiemetic medicines, rhinitis medicines, or anti-allergic medicines.

Ⅳ.Others:

1. Store properly to prevent children from accidentally taking this drug.
2. Avoid direct sunlight.

3. Do not exceed the stated dose.
4. Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose.
   (Must be indicated for solutions.)
5. The medicine must not be used with alcoholic beverages.
6. The medicine may cause drowsiness, so do not drive or operate dangerous machinery.
7. Avoid taking medicines or drinks containing caffeine. Too much caffeine can cause nervousness, excitement and insomnia, and often results in tachycardia.
   (Must be indicated for preparations containing caffeine in category C.)

F. Dosage and Administration

I. Anti-allergic Preparations:

Adults and children aged 12 years and over.	Three to four times a day, with at least four hours of dosing interval.
Children 6 to less than 12 years of age.	1/2 of adult dosage.
Children 3 to less than 6 years of age.	1/4 of adult dosage.
Children under the age of 3 years.	Consult your doctor.

Ⅱ. Preparations containing clemastine (fumarate) in Table 1 category A:

Adults and children aged 12 years and over.	Twice a day
Children under the age of 12 years.	Consult your doctor.

Ⅲ.Preparations containing triprolidine hydrochloride in Table 1 category A:

Adults and children aged 12 years and over.	Three to four times a day, with at least four hours of dosing interval.
Children 6 to less than 12 years of age.	1/2 of adult dosage.
Children under the age of 6 years.	Consult your doctor.

Ⅳ.For oral solutions (including syrups), the one-time dose for an adult must be 5 ml or more. The maximum package of selling unit may not exceed three days.

G. Warnings

I.After taking the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

Body part	Side effects
Nervous system	Fatigue; excitement
Other	Dry mouth; visual problems.

Ⅱ.After taking the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

1. Any discomfort occurs.
2. If symptoms are not improved after taking this medicine for several days.

Ophthalmic drug products

A. Scope

(I) The guidelines are applicable to any medication that is applied to the eyes or used to relieve discomfort caused by mild eye irritation or eye redness, eye strain, eye pruritus or burning sensation, and irrigation caused by dry eyes or medications used to flush the eyes.

(II) The guidelines are not applicable to contact lens solutions.

B. Active ingredients

(I) Active ingredient and dose:

1. The active ingredients stipulated in Table 1 are applicable to this guideline.
2. Table 1 stipulates the maximum dose or the upper and lower limits of composing concentration for each active ingredient, except for Category G.
3. Indications are stipulated in Table 1.

Table 1. Active ingredient and dose

Category	Group	Active ingredients	Maximum dose or optional composing concentration (%)	Use (indications)
A	1	Ephedrine hydrochloride	0.123 (Fixed dose)	Temporary relief of discomfort caused by slight eye irritation, or eye redness.
		Naphazoline hydrochloride	0.01-0.03	
		Phenylephrine hydrochloride	0.08-0.20	
		Tetrahydrozoline hydrochloride	0.01-0.05	
	2	Ephedrine hydrochloride	0.1	
		Epinephrine	0.003	
		Epinephrine hydrochloride *1	0.003 (as Epinephrine)	
		dl-Methylephedrine hydrochloride	0.1	
		Naphazoline hydrochloride	0.003	
		Naphazoline nitrate	0.003	
		Phenylephrine hydrochloride	0.1	
		Tetrahydrozoline hydrochloride	0.05	
B		Neostigmine methylsulfate	0.005	

Table 1. Active ingredient and dose (continued)

Category	Group	Active ingredients	Maximum dose or optional composing concentration (%)	Use (indications)
C	1	ε-Aminocaproic acid	5	Temporary relief of discomfort caused by slight eye irritation.
	2	Allantoin	0.3	
	3	Berberine hydrochloride	0.025	
		Berberine sulfate	0.025	
	4	Sodium azulene sulfonate	0.02	
	5	Dipotassium glycyrrhizinate	0.25	
	6	Zinc lactate	0.25	
		Zinc sulfate	0.25	
	7	Lysozyme hydrochloride	0.5 (potency)	
D		Chlorpheniramine maleate	0.03	Eye pruritus
		Diphenhydramine hydrochloride	0.05	
E	1	Sodium flavin adenine dinuleotide	0.05	Eye strain
	2	Cyanocobalamin	0.02	
	3	Retinol acetate	50,000units/ 100ml	
		Retinol palmitate	50,000units/ 100ml	
	4	Pyridoxal phosphate	0.1	
		Pyridoxine hydrochloride	0.1	
	5	Calcium pantothenate	0.1	
		Panthenol	0.1	
		Sodium pantothenate	0.1	
	6	Tocopherol Acetate *2	0.05 *2	
F	1	L-Magnesium aspartate	1	Eye strain
		L-Potassium aspartate	1	
		L-Potassium and magnesium aspartate (equal mixture)	2	
	2	Taurine (Aminoethylsulfonic acid)	1	
	3	Sodium chondroitin sulfate	0.5	
G		Calcium chloride	—	Eye flush
		Magnesium sulfate	—	
		Potassium phosphate, monobasic	—	

		Potassium chloride	—	
		Sodium bicarbonate	—	
		Sodium carbonate	—	
		Sodium carbonate, dried	—	
		Sodium chloride	—	
		Sodium phosphate, dibasic	—	
		Sodium phosphate, monobasic	—	

Table 1. Active ingredient and dose (continued)

Category	Group	Active ingredients	Maximum dose or optional composing concentration (%)	Use (indications)
H	1	(a) Cellulose derivatives		Temporary relief of burning sensation and irritation caused by dry eyes.
		Carboxymethylcellose sodium	0.2-2.5	
		Hydroxyethyl cellulose	0.2-2.5	
		Hydroxypropyl methylcellose	0.2-2.5	
		Methylcellulose	0.2-2.5	
		(b) Dextran 70	0.1	
		(c) Gelatin	0.01	
		(d) Polyols liquid		
		Glycerin	0.2-1.0	
		Polyethylene glycol 300	0.2-1.0	
		Polyethylene glycol 400	0.2-1.0	
		Polysorbate 80	0.2-1.0	
		Propylene glycol	0.2-1.0	
		(e) Polyvinyl alcohol	0.1-4.0	
		(f) Povidone (polyvinylpyrrolidone)	0.1-2.0	
	2	(a) Lanolin Preparations		
		Anhydrous lanolin	1-10	
		Lanolin	1-10	
		(b) Oleaginous Ingredients		
		Light mineral oil	50	
		Mineral oil	50	
		Paraffin	5	
		Petrolatum	100	
		White ointment	100	
		White petrolatum	100	
		White wax	5	
		Yellow wax	5	

*1. Can be substituted with epinephrine solution included in various countries' Pharmacopoeias.

*2. Includes dl-α-Tocopherol acetate and d-α-Tocopherol acetate. (0.05 = 75.43 IU/mL)

(II) Combination rules (see Table 2):

1. Ophthalmic preparations (1):

(1) Essential composing ingredients: The active ingredients in Table 1 Category A Group 1. The formula for ophthalmic preparations (1) must (and can only) contain one essential composing ingredient.

(2) Optional composing ingredients: Zinc sulfate in Table 1 Category C Group 6 and the active ingredients in Category H Group 1; can be used in combination with the above essential composing ingredients as a compound preparation.

(3) When used in combination with the ingredients in Table 1 Category H Group 1, can be combined with at most three active ingredients.

2. Ophthalmic preparations (2):

(1) Essential composing ingredients: The active ingredients in Category A Group 2, Category C, Category D, Category E Group 1, Group 2, Group 3, and Category F Group 1. The ophthalmic preparations (2) must contain at least one essential composing ingredient.

(2) Optional composing ingredients: The active ingredients in Table 1 Category B, Category E Group 4, Group 5, Group 6, and Category F Group 2 and Group 3.

(3) In the formulation of ophthalmic preparations (2), the aforementioned essential composing ingredients can be used in combination with each other, and can be used with the optional composing ingredients mentioned above as a compound preparation.

(4) When in combination with the active ingredient of Table 1 Category A Group 2 and Category D, at most one active ingredient of that Group (Category) can be combined.

(5) When in combination with Table 1 Category C, Category E or Category F, at most three active ingredients of each Category can be

combined, and at most one active ingredient of each Group can be combined.

3. Artificial tears (1):

(1) Essential composing ingredients: The active ingredients in Table 1 Category F Group 2, Group 3, and Category G. The formula for artificial tears (1) must contain at least one essential composing ingredient.

(2) Optional composing ingredients: The active ingredients in Table 1 Category F Group 1 and Category H Group 1 (a), (e), (f).

(3) In the formulation for artificial tears (1), the aforementioned essential composing ingredients can be used in combination with each other, and can be used with the optional composing ingredients mentioned above as a compound preparation.

4. Artificial tears (2):

(1) The essential composing ingredient shall be an active ingredient in Table 1 Category H Group 1. The formula for artificial tears (2) must contain one essential composing ingredient; there can be at most three active ingredients.

(2) Dextran 70 in Category H Group 1 (b) shall be used in combination with an active ingredient in Category H Group 1 (d), and must not be used as a single-ingredient preparation.

5. Artificial tears (3):

(1) The essential composing ingredient shall be an active ingredient in Table 1 Category H Group 2. The formula for artificial tears (3) must contain at least one essential composing ingredient; and can be used in combination with one or more active ingredients as a compound preparation.

(2) The ingredients in Category H Group 2 (a) must be used in combination with an active ingredient in Category H Group 2 (b), and must not be used as a single-ingredient preparation.

(3) Light mineral oil, mineral oil, paraffin, white wax and yellow wax of Category H Group 2 (b) shall be used in combination with the active ingredient(s) in Category H Group 2, and must not be used as a single-ingredient preparation.

6. Eyewash (1):

(1) Essential composing ingredients: The active ingredients in Table 1 Category C and Category D. The formula for Eyewash (1) shall contain at least one essential composing ingredient.

(2) Optional composing ingredients: The active ingredients in Table 1 Category E and Category F.

(3) In the formulation of Eyewash (1), the aforementioned essential composing ingredients can be used in combination with each other, and can be used with the optional composing ingredients mentioned above as a compound preparation.

(4) When in combination with Category C, Category E or Category F, at most three active ingredients from each Category can be combined, and at most one active ingredient from each Group can be used.

(5) When in combination with the active ingredients of Table 1 Category D, at most one active ingredient from that Category can be combined.

7. Eyewash (2):

(1) Essential composing ingredients: The active ingredients in Table 1 Category G.

(2) The formula can only contain one essential composing ingredient.

(Ⅲ) Combination dose of active ingredients (see Table 3):

1. Except for the ingredients in Table 1 Category G, the Combination dose of active ingredients must not exceed the maximum concentration or the upper limit of the composing concentration stipulated in Table 1.
2. The combination amount of the ingredients in Table 1 Category G (inorganic salts) depends on the properties of the preparation, and thus is not stipulated.
3. Ophthalmic preparations (1)
   (1) The composing concentration of each active ingredient shall meet the maximum amount or the upper and lower limits of the combination amount stipulated in Table 1.
   (2) The dose of ephedrine hydrochloride in Table 1 Category A Group 1 is a fixed dose.
4. Ophthalmic preparations (2):
   (1) When the formula contains ingredients in Table 1 Category A Group 2, Category B, Category C, Category D, Category E Group 1, Group 2, Group 3 or Category F Group 1:
      a. If the preparation contains one essential composing ingredient, the minimum composing concentration of the above ingredients is 1/2 of the maximum dose stipulated in Table 1.
      b. If the preparation contains two or more essential composing ingredients, the minimum composing concentration of the above ingredients is 1/5 of the maximum dose stipulated in Table 1.
   (2) When the formula contains the active ingredients in Table 1 Category E Group 4, Group 5, Group 6 or Category F, Group 2, Group 3, the minimum composing concentration of the combination ingredient is 1/10 of the maximum dose stipulated in Table 1.

(3) For ingredients in Table 1 Category C, Category E or Category F, when two or more ingredients in the same Category are combined, the combination coefficient of that Category cannot be greater than 2. In other words, the sum of the ratio of the composing concentration to the maximum dose of each composing ingredient in the same Category cannot be greater than 2.

5. Artificial tears (1):

(1) When the formula contains the active ingredients in Table 1 Category F, the minimum composing concentration of the composing ingredient is 1/10 of the maximum dose stipulated in Table 1; when two or more ingredients from that Category are combined, the combination coefficient cannot be greater than 2. In other words, the sum of the ratio of the composing concentration to the maximum dose of each composing ingredient in that Category cannot be greater than 2.

(2) When an active ingredient in Category H Group 1 (a) is used, the combination amount of the active ingredient must follow the upper and lower limits of the combination amount stipulated in Table 1.

(3) When polyvinyl alcohol in Category H Group 1 (e) is used, the minimum combination amount is 0.20%; when povidone in Category H Group 1 (f) is used, the minimum combination amount is 0.25%.

6. For artificial tears (2) and artificial tears (3), the composing concentration for each active ingredient must meet the maximum amount or the upper and lower limits of the combination amount stipulated in Table 1.

7. The pH values of artificial tears (1), (2) and (3) are between 5.5 and 8.0, and the osmotic pressure ratios are between 0.85 and 1.55 (to the osmotic pressure of normal saline).

8. Eyewash (1):

(1) The maximum combination amount of each active ingredient in Table 1 Category C, Category E, Category D and Category F is 1/10 of the maximum amount stipulated in Table 1.

(2) When an active ingredient in Table 1 Category C or Category D is used, the minimum combination amount of the composing ingredient is 1/50 of the maximum amount stipulated in Table 1.

(3) When an active ingredient in Table 1 Category E or Category F is used, the minimum combination amount of the composing ingredient is 1/100 of the maximum amount stipulated in Table 1.

(4) For ingredients in Table 1 Category C, Category E or Category F, when two or more ingredients in the same Category are combined, the combination coefficient for that Category cannot be greater than 2/10. In other words, the sum of the ratio of the composing concentration to the maximum dose of each active ingredient in the same Category cannot be greater than 2/10.

9. The pH values of Eyewash (1) and (2) are between 5.5 and 8.0, and the osmotic pressure ratios are between 0.60 and 1.55 (to the osmotic pressure of normal saline).

10. For the artificial tears and Eyewash containing only the ingredients in Table 1 Category G (inorganic salts), the dose is based on the physical properties, and the pH value and osmotic pressure ratio must meet the specifications for artificial tears and Eyewash.

C. Dosage form

Limited to eye ointment, ophthalmic gel, ophthalmic solution, Eyewash, ophthalmic suspension.

D. Use (indications)

(1) The indications for each Category shall be indicated in accordance with the active ingredients of each Category used in the preparation. The indications for compound preparations can be combined.

(2) The indications for Eyewash must be indicated as "for rinsing the eyes."

(3) The indications of artificial tears must be indicated as "temporary relief of burning sensation and irritation caused by dry eyes;" if the preparation is preservative-free, it can also be indicated as "temporary relief of discomfort caused by wearing contact lenses."

E. Precautions

I. Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product.

(II)People developing contact dermatitis of eyelid or keratoconjunctivitis after several weeks of use.

(Must be indicated for preparations using mercury compound as a preservative agent.)

II.Under the following conditions, consult your doctor before use:

(I) People who are undergoing treatment or using prescribed eye drops.

III.Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I)People with glaucoma

(Must be indicated for the preparations containing vasoconstrictive ingredients in Table 1 Category A.)

IV.Others

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III) Wash hands before use.

(IV) Follow instructions on label.

(Ⅴ) Do not continue to use in the following situations.

1. Expired eye drops.
2. 28 days after opening.
   (Must be indicated for bottled eye drops.)
3. Unfinished one-time solution.
   (Must be indicated for unit-dose packages.)
4. When the solution is turbid, discolored or contains foreign materials.

(Ⅵ) Must be used within 24 hours.
(Must be indicated for re-cap preservative-free disposable eye drops.)

(Ⅶ) To avoid contamination, do not touch the dropper tip, and avoid sharing the eye drops with others or use other containers.

(Ⅷ) If you need to use two or more eye drops at the same time, follow the following instructions to avoid affecting the efficacy:

1. When using both eye drops and eye ointment, apply the eye drops first, and then apply the eye ointment more than 10 minutes later.
2. When using two types of eye drops, an interval of five minutes or more is recommended.

(Ⅸ) Do not use eye drops containing preservatives or suspensions when wearing contact lenses.
(Must be indicated for eye drops containing preservatives and suspensions.)

(Ⅹ) Eye ointment (gel) may cause blurred vision, use just before bed is recommended.

(Must be indicated for eye ointment and ophthalmic gel.)

(XI) Excessive use will increase eye redness or swelling.

(Must be indicated for preparations containing vasoconstrictive ingredients in Table 1 Category A.)

F. Dosage and Administration

I. Ophthalmic preparations:

Three to four times a day	1 to 2 drops at a time.

II. Artificial tears:

(I) Artificial tears containing preservatives:

Three to four times a day	1 to 2 drops at a time.

(II) Artificial tears without preservatives.

Use when needed.	1 to 2 drops at a time.

III. Eyewash:

3 to 6 times a day	The dosage for each time must be clearly indicated. The Eyewash will come with eyewash aids, such as an eyewash cup, and the dosage must be clearly indicated. Before each use, quickly rinse the eye cup with water, to avoid contamination at the edge of the cup or inside the cup. Fill the cup with a single dose of Eyewash and bring it close to the eye to be treated. Tightly press the cup to the eye to prevent the liquid from leaking. Slightly tilt your head back, open the eyelid, and roll your eyeball so that the Eyewash can fully rinse the eye. Wash the cup with clean water

	after use. If you use a slim syringe to wash your eye when needed, use the pressure control on the bottle to control the rate of solution.

G. Warnings

I. After using the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) If symptoms are not improved after taking this medicine for three days.

(II) Severe eye pain, persistent blurred vision or persistent redness, swelling, heat or irritation after use.

(III) Any discomfort occurs.

(IV) Allergic reactions, such as skin pruritus, urticaria, abnormal sound, sore throat, difficulty breathing, palpitations or unconsciousness.

(This must be indicated for preparations containing lysozyme hydrochloride.)

Table 2 Combination rules

Active ingredients \ Preparation name			Ophthalmic preparations		Artificial tears			Eyewash		Notes
			(1)	(2)	(1)	(2)	(3)	(1)	(2)	
Category A	Group 1	Vasoconstrictors (4 ingredients)	◎	×	×	×	×	×	×	Can be combined with at most one ingredient.
	Group 2	Vasoconstrictors (8 ingredients)	×	◎	×	×	×	×	×	Can be combined with at most one ingredient.
Category B		Neostigmine methyl sulfate	×	○	×	×	×	×	×	
Category C	Group 1	ε-Aminocaproic acid	×	◎	×	×	×	◎	×	Can be combined with at most three ingredients, but only one ingredient from each item.
	Group 2	Allantoin								
	Group 3	Berberines (2 ingredients)								
	Group 4	Sodium azulene sulfonate								
	Group 5	Dipotassium glycyrrhetinate								
	Group 6	Zinc sulfate	○							
		Zinc lactate	×							
	Group 7	Lysozyme hydrochloride	×							
Category D		Antihistamines (2 ingredients)	×	◎	×	×	×	◎	×	Can be combined with at most one ingredient.
Category E	Group 1	Sod. Flavin adenine dinucleotide	×	◎	×	×	×	○	×	Can be combined with at most three ingredients, but only one ingredient from each group.
	Group 2	Cyancobalamin								
	Group 3	Retinols (2 ingredients)								
	Group 4	Pyridoxine hydrochloride		○						
		Pyridoxal phosphate								
	Group 5	Pantothenates (3 ingredients)								
	Group 6	Tocopherol acetate								
Category F	Group 1	Aspartates (3 ingredients)	×	◎	○	×	×	○	×	Can be combined with at most three ingredients, but only one ingredient from each group.
	Group 2	Taurine(Aminoethyl sulfonic acid)		○	◎					
	Group 3	Sodium chondroitin sulfate								
Category G		Inorganic salts (10 ingredients)	×	×	◎	×	×	×	◎	
Category H	Group 1	(a) Cellulose derivatives (4 ingredients)	○	×	○	◎	×	×	×	
		(b)Dextran			×					

		(c)Gelatin								
		(d) Polyos liquid (5 ingredients)								
		(e)Polyvinyl alcohol			○					
		(f)Povidone								
	Group 2	(a) Lanolin preparations (2 ingredients)	×	×	×	×	◎	×	×	
		(b) Oleaginous ingredients (8 ingredients)								
Notes			See page 5 for the combination rules.			See page 6 for the combination rules.	See page 6 for the combination rules.		Can only contain one ingredient.	

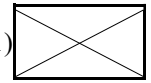
◎: Essential composing ingredient ○: Optional composing ingredient ×: Non-composing ingredient.

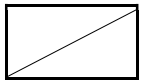
Table 3 Combination coefficients

Category	Group	Preparations / Active ingredients	Ophthalmic preparations (1) Each ingredient	Ophthalmic preparations (2) Each ingredient: Essential composing ingredient: Combined with any one ingredient in the preparation	Ophthalmic preparations (2) Each ingredient: Essential composing ingredient: Combined with at least two ingredients in the preparation	Ophthalmic preparations (2) Each ingredient: Optional composing ingredient (any number of ingredients)	Ophthalmic preparations (2) Each ingredient: Combination coefficient for at least two ingredients in the same Category	Artificial tears (1) Each ingredient	Artificial tears (1) Combination coefficient for at least two ingredients in the same Category	Artificial tears (2) Each ingredient	Artificial tears (3) Each ingredient	Eyewash (1) Each ingredient	Eyewash (1) Combination coefficient for at least two ingredients in the same Category	Eyewash (2) Each ingredient	Notes
A	1	Vasoconstrictors	Based on Table 1												Can only contain one ingredient.
	2	Vasoconstrictors		1/2≦ ≦1	1/5≦ ≦1										Can only contain one ingredient.
B		Neositigmine methyl sulfate		1/2≦ ≦1	1/5≦ ≦1										
C	1 – 7	Anti-inflammatory astringents	Zinc sulfate From Table 1	1/2≦ ≦1	1/5≦ ≦1		≦2					1/50 ≦ ≦ 1/10	≦2/10		Can contain at most three ingredients, but only one ingredient from each group.
D		Antihistamines		1/2≦ ≦1	1/5≦ ≦1							1/50 ≦ ≦ 1/10			Can only contain one ingredient.
E	1	Sodium flavin adenine dinucleotide		1/2≦ ≦1	1/5≦ ≦1		≦2					1/100 ≦ ≦ 1/10	≦2/10		Cancontain at most three ingredients, but only one ingredient from each group.
	2	Cyanocobalamin													
	3	Retinols													
	4	Pyridoxine hydrochloride Pyridoxal phosphate				1/10≦ ≦1						1/100 ≦ ≦ 1/10			
	5	Pantothenatos													

	6	Tocopherol acetate													
F	1	Aspartates		1/2≦ ≦1	1/5≦ ≦1		≦2	1/10≦ ≦1	≦2			1/100 ≦ ≦ 1/10	≦2/10		Can contain at most three ingredients, but only one ingredient from each group.
	2	Aminoethyl sulfonic acid				1/10≦ ≦1		1/10≦ ≦1				1/100 ≦ ≦ 1/10			
	3	Sodium chondroitin sulfate													
G		Inorganic salts						The dose is not stipulated.	The dose is not stipulated.					The dose is not stipulated.	For preparations containing only the active ingredients in Category G, the dose is based on the physical properties.
H	1	(a)Cellulose derivatives	Based on Table 1					From Table 1	The dose is not stipulated.	Based on Table 1					
		(b)Dextran 70 (c)Gelatin (d)Polyols liquid													
		(e)Polyvinyl alcohol (f)Povidone						0.20% ≦ ≦1(4%) 0.25% ≦ ≦1(2%)	The dose is not stipulated.						
	2	(a)Lanolin preparation (b)Oleaginous ingredients									Based on Table 1				

Notes			1.pH: 5.5-8.0; Osmotic pressure ratio: 0.85-1.55; (to the osmotic pressure of normal saline.) 2. For preparations containing only the active ingredients in Category G, the dose is based on the physical properties.	pH: 5.5-8.0; Osmotic pressure ratio: 0.60-1.55; (to the osmotic pressure of normal saline.)	For preparations containing only the active ingredients in Category G, the content is based on the physical properties.	

Note 1)  : Cannot be composed in the preparation.

 : No combination rules

Note 2)  : Essential composing ingredient

Drug products for motion sickness

A. Scope

The guideline applies to all oral preparations used to prevent or alleviate motion sickness caused by transportation.

B. Active ingredients

I. Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the maximum single dose and the maximum daily dose of each active ingredient in category A, B; and the upper and lower limit of the daily dose for each active ingredient in category C.

Table 1. Active ingredient and dose

Category	Group	Active ingredients	Maximum single dose (mg)	Maximum daily dose (mg)
A		Cyclizine hydrochloride	50	150
		Brompheniramine maleate	4	12
		Chlorpheniramine maleate	4	12
		Dexchlorpheniramine maleate	2	6
		Dimenhydrinate	60	240
		Diphenhydramine hydrochloride	25-50	150
		Diphenhydramine salicylate	40	160
		Diphenylpyraline hydrochloride	4	12
		Meclizine hydrochloride	50	50
B		Caffeine	50	150
		Caffeine anhydrous	50	150

Table 1. Active ingredient and dose (continued)

Category	Group	Type		Daily dose (mg)
C	1	Vitamin B_1		1.8-30
		Active ingredients	Bisbentiamine Bisibutiamine Cetotiamine hydrochloride Cycotiamine Dibenzoyl thiamine Dibenzoyl thiamine hydrochloride Fursultiamine hydrochloride Octotiamine Prosultiamine Thiamine hydrochloride Thiamine mononitrate Thiamine dicetylsulfate Thiamine disulfide	
	2	Vitamin B_2		2.25-10
		Active ingredients	Riboflavin (Vitamin B_2) Riboflavin butyrate Riboflavin sodium phosphate	
	3	Vitamin B_6		5-50
		Active ingredients	Pyridoxine hydrochloride	
	4	Niacinamide (Nicotinamide)		12-60
	5	Calcium pantothenate		5-30

II. Combination rules (see Table 2):

(I) Essential composing ingredients: The active ingredients in Category A of Table 1. The formula must contain one essential composing ingredient.

(II) Optional composing ingredients: The active ingredients in Category B and C of Table 1, which can be used in combination with the essential composing ingredients.

(III) Cyclizine hydrochloride in Category A of Table 1 is limited to single-ingredient preparation only.

(IV) Ingredients in Category B can be combined at most one active ingredient.

III. Combination dose of active ingredients (see Table 2):

(I)Ingredients in Category A of Table 1:

1. The one-time maximum dose and daily maximum dose of each active ingredient must not exceed the maximum single dose and maximum daily dose stipulated in Table 1.
2. The combination coefficient for the ingredients in Category A must be between 1 and 1/2.
3. Combination coefficient = X/mX

   X: the daily dose of ingredient x in Category A.

   mX: the maximum daily dose of ingredient x in Category A.

(II)When the formula contains an ingredient in Category B of Table 1:

1. The one-time maximum dose and daily maximum dose of each active ingredient must not exceed the maximum single dose and maximum daily dose stipulated in Table 1.
2. When the formula contains an active ingredient in Category B, the combination coefficient of this Category must be between 1 and 1/5.
3. Combination coefficient = X/mX

   X: the daily dose of ingredient x in Category B.

   mX: the maximum daily dose of ingredient x in Category B.

(III)When the formula contains an ingredient in Category C of Table 1:

1. When an active ingredient in one Group is composed, the dose of the ingredient shall follow the upper and lower limits of the daily dose stipulated in Table 1.

2. When two or more ingredients in Group 1 and Group 2 of Category C are composed, the sum of the combination coefficient cannot be greater than 1. In other words, the sum of the ratio of daily dose to the maximum daily dose of each ingredient shall not be greater than 1.

3. Sum of combination coefficients $= \Sigma (X_i/mX_i)$

$= (X_1 / mX_1)+(X_2 / mX_2)+\ldots\ldots+(X_n / mX_n)$

X_i: the daily dose of ingredient i in Group 1 (or Group 2) of Category C

mX_i: the maximum daily dose of ingredient i in Group 1 (or Group 2) of Category C

n: Number of the composed ingredients in Group 1 (or Group 2) of Category C

Table 2 Combination rules and combination coefficients

Active ingredients			Combination rules	Combination coefficient		Notes
				Combing one ingredient in the same Category	Combing at least two ingredients in the same Category	
Category A	Antihistamine		◎	1/2≦ ≦1		Cyclizine hydrochloride is limited to single-ingredient preparation only.
Category B	Caffeine-type		○	1/5≦ ≦1		May combine at most one of the ingredients.
Category C	Group 1	Vitamin B_1	○	Based on Table 1	≦1	Based on the upper and lower limits of the daily dose stipulated in Table 1.
	Group 2	Vitamin B_2		Based on Table 1	≦1	
	Group 3	Vitamin B_6		Based on Table 11		
	Group 4	Niacinamide		Based on Table 11		
	Group 5	Calcium Pantothenate		Based on Table 1		

C. Dosage form

Limited to tablets, film coated tablets, sugar coated tablets, capsules, soft capsules, oral solutions, syrups, powders, granules and fine granules.

D. Use (indications)

Prevention or relief of symptoms caused by motion sickness (car sickness, seasickness, airsickness), such as dizziness, nausea, vomiting or headache.

E. Precautions

Ⅰ. Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product.

(II) Breastfeeding women.

(Must be indicated for preparations containing diphenhydramine hydrochloride or diphenhydramine salicylate.)

Ⅱ. Under the following conditions, consult your doctor before use:

(I) Children under the age of 6 years.

(II)Children under the age of 12 years.

(Must be indicated for preparations containing meclizine hydrochloride and caffeine types in Category B.)

(Ⅲ) People with severe metabolic liver or kidney disease.

(Ⅳ)You have a history of the following diseases: heart disease, hypertension, diabetes, hyperthyroidism or kidney disease.

(Ⅴ)You have a history of respiratory disease: such as chronic bronchitis, emphysema, chronic lung disease, shortness of breath, or difficulty breathing; and people with glaucoma, or people with difficulty in urination due to prostatic hyperplasia.

Ⅲ. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I)Pregnant women, women who might be pregnant, and breastfeeding women.

(II)Adults aged 65 years and over.

(III) People who are under treatment by physician and taking medications.

(IV) People who are taking sedatives or sleeping medicines.

(V) People who are taking other motion sickness medicines, common cold medicines, antitussive or expectorant medicines, rhinitis medicines, or anti-allergic medicines.

(VI) People who are uncertain how to take the medicine.

IV. Others:

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III)Do not exceed the stated dose.

(IV)Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose. (Must be indicated for solutions.)

(V) The medicine must not be used with alcoholic beverages.

(VI)The medicine may cause drowsiness, so do not drive or operate dangerous machinery.

(VII)Avoid taking medicines or drinks containing caffeine. Too much caffeine can cause nervousness, excitement and insomnia, and often results in tachycardia. To avoid dependence and liver and kidney damage, it must not be used for a long time.

(Must be indicated for preparations containing caffeine types in Category B.)

F. Dosage and Administration

I. Motion sickness preparations

Adults and children aged 12 years and over.	To prevent car sickness, seasickness and airsickness, take this medicine 30 minutes before the ride (30 to 60 minutes or 60 minutes, either description shall be indicated), ○○ /time. If necessary, take it again on the ride or when symptoms appear. The interval must be ○ hours or more. Do not take more than ○ times within 24 hours. (Please determine the administration interval and maximum daily dose according to the property of the drug product.)
Children 6 to less than 12 years of age.	1/2 of adult dosage.
Children under the age of 6 years.	Consult your doctor.

II. Preparations containing meclizine hydrochloride

Adults and children aged 12 years and over.	To prevent car sickness, seasickness and airsickness, take this medicine 30 minutes before the ride (30 to 60 minutes or 60 minutes, either description shall be indicated), ○○ /time and once a day.
Children under the age of 12 years.	Consult your doctor.

G. Warnings

I. After taking the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist:

Body part	Side effects
Nervous system	Drowsiness, fatigue, excitement
Skin	Rash, redness, pruritus.
Other	Headache, blush, palpitations, difficulty urinating, dizziness, mood swing, restlessness, dry mouth, constipation or diarrhea, visual disturbance.

II. After taking the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Any discomfort occurs.

(II) If symptoms are not improved after taking this medicine for several days.

Anthelmintic drug products

A. Scope

This guideline is applicable to preparations for elimination of pinworms.

B. Active ingredients

I. Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the Maximum daily dose of each active ingredient.

Table 1. Active ingredient and dose

<table>
<tr><td colspan="2">Active ingredients</td><td>Maximum daily dose (mg)</td></tr>
<tr><td colspan="2">Pyrantel pamoate</td><td>1,000(base)</td></tr>
<tr><td colspan="2">Pyrvinium pamoate</td><td>250(base)</td></tr>
<tr><td colspan="2">Piperazine</td><td rowspan="2">2,000
(as Piperazine hexahydrate)</td></tr>
<tr><td>Active ingredients</td><td>Piperazine adipate
Piperazine citrate
Piperazine hexahydrate
Piperazine maleate
Piperazine phosphate</td></tr>
<tr><td colspan="2">Mebendazole</td><td>100</td></tr>
</table>

II. Combination rules

The drugs governed by this guideline are limited to single-ingredient preparations only.

III. The combination dose of active ingredients

The one-time dose of each active ingredient must be calculated based on body weight (except Piperazine and Mbendazole), and the

maximum one-day dose must not exceed the maximum daily dose specified in Table 1.

C. Dosage form

Limited to tablets, film coated tablets, sugar coated tablets, oral solutions, syrups, chewable tablets, suspension solutions, powders for syrup, granules for internal use, and powders.

D. Use (indications)

Elimination of pinworms.

E. Precautions

I . Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product.

II. Under the following conditions, consult your doctor before use:

(I) Children under the age of 3 years or 12 kg.

(II) People with liver dysfunction.

(III) People with renal dysfunction.

(Must be indicated for preparations containing Pyrvinium.)

(IV) People with epilepsy.

(Must be indicated for preparations containing Piperazine.)

III .Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Pregnant women, women who might be pregnant, or breastfeeding women.

(II) Patients with severe malnutrition or anemia.

(Must be indicated for preparations containing Piperazine.)

IV . Other

(I) Do not exceed the stated dose.

(II) Store properly to prevent children from accidentally taking this drug.

(III) Avoid direct sunlight.

(IV) Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose

(Must be indicated for the preparations of solution dosage forms.)

(Ⅴ) If any member of the family is infected with pinworms, the whole family must be treated.

(Ⅵ) Transient abdominal pain, diarrhea and vomiting might happen when infected with a large number of pinworms or when the pinworms are eliminated.

(Ⅶ) After taking the preparation, the stool might be red, and sometimes the vomit may be red as well.

(Must be indicated for preparations containing Pyrvinium.)

F. Dosage and Administration

I. Preparations containing Pyrantel pamoate

Adults and children aged 3 years or 12 kg over.	1.Please calculate the one-time dose according to your weight: take 10 mg/kg each time, and do not exceed 1000 mg/day. 2.If symptoms have not been relieved after 2 weeks, or if there is another infection, you may take one more dose. 3.Medicine can be taken with food, milk or juice.
Children under the age of 3 years or less 12 kg.	Consult your doctor.

II. Preparations containing Pyrvinium pamoate.

Adults and children aged 3 years or 12 kg over.	1. Please calculate the one-time dose according to your weight: please take 5 mg/kg each time, and do not exceed 250 mg/day. Just one dosage, there is no need to take the second one. 2. Take with meal or before bedtime.
Children under the age of 3 years or less 12 kg.	Consult your doctor.

III. Preparations containing Piperazine

Adults and children aged 15 years and over	1. The daily dose of 2000 mg can be divided into 1 to 2 times per day. It must be administered every day for a whole week (but not more than seven days). 2. Taking preparation with empty stomach.
Children 11 to less than 15 years of age.	2/3 of adult dosage.
Children 8 to less than 11 years of age.	1/2 of adult dosage.
Children 5 to less than 8 years of age.	1/3 of adult dosage.
Children 3 to less than 5 years of age.	1/4 of adult dosage.
Children under the age of 3 years.	Consult your doctor.

IV. Preparations containing Mebendazole

Adults and children aged 3 years or 12 kg over.	1. 100 mg each time. 2. If symptoms have not been

	relieved after 2 weeks, or if there is another infection, you may take one more dose. 3. The medicine need not be taken with empty stomach. It can be taken at any time.
Children under the age of 3 years or less 12 kg.	Please consult your doctor.

G. Warnings

I. After taking the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

(I) The following information must be indicated for the preparations containing Pyrantel:

Body part	Side effects
Gastrointestinal tract	Nausea, vomiting, diarrhea, spastic abdominal pain, and anorexia.
Other	Headache, insomnia, dizziness, drowsiness, increased excitement, and rashes.

(II) The following information must be indicated for the preparations containing Pyrvinium:

Body part	Side effects
Gastrointestinal tract	Nausea, vomiting, abdominal pain, and burping.
Other	Temporary headache and photosensitivity.

(III) The following information must be indicated for the preparations containing Piperazine:

Body part	Side effects

Gastrointestinal tract	Vomiting, abdominal pain, diarrhea, and burping.
Other	Headache, dizziness, fever, and joint pain.

II. After taking the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Any discomfort occurs, or there is no improvement in the symptoms.

(II) The following information must be indicated for the preparations containing Mebendazole:

Body part	Side effects
Nervous system	Drowsiness, headache, and dizziness.
Other allergic reactions	Skin redness, prurigo, urticaria, and angioedema.

(III) The following information must be indicated for the preparations containing Piperazine:

Body part	Side effects
Nervous system	Ataxia, tremors, chorea-like movement disorders, muscle weakness, abnormal reflexes and perception, blurring of vision, paralytic strabismus, abnormal EEG, sense of separation, memory loss, and sense of fatigue.
Other	Allergic reactions (such as urticaria, erythema Multiforme, etc.).

Laxatives

A. Scope

I. This guideline applies to oral preparations or suppositories intended to stool softening or constipation relief.

II. This guideline does not apply to preparations made only of crude drug ingredients in Category A Group 1(c), Category C and Category D.

B. Active ingredients

I. Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the maximum single dose and the maximum daily dose of each active ingredient in category A; the upper and lower limit of the maximum single dose and the maximum daily dose for each active ingredient in category B; and the maximum daily dose of each active ingredient in category C and Category D.

Table 1. Active ingredient and dose

<table>
<tr><td>Category</td><td>Group</td><td>Active ingredients</td><td colspan="2">Maxiumum single dose (g)</td><td colspan="2">Maximum daily dose (g)</td></tr>
<tr><td rowspan="8">A</td><td rowspan="8">1</td><td>(a)Bisacodyl</td><td colspan="2">0.015</td><td colspan="2">0.015</td></tr>
<tr><td>(b)Sennosides *2</td><td colspan="2">0.024</td><td colspan="2">0.024</td></tr>
<tr><td rowspan="2">Active ingredients</td><td colspan="2">Maxiumum single dose *1 (g)</td><td colspan="2">Maximum daily dose *1 (g)</td></tr>
<tr><td>Extracts (amount converted from original crude drug ingredient)</td><td>Powders</td><td>Extracts (amount converted from original crude drug ingredient)</td><td>Powders</td></tr>
<tr><td>I Crude drug ingredient</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td>Aloe</td><td>0.38</td><td>0.38</td><td>0.75</td><td>0.75</td></tr>
<tr><td>Cascara sagrada</td><td>1.5</td><td>—</td><td>3</td><td>—</td></tr>
</table>

Table 1. Types of active ingredients (continued)

Category	Group	Active ingredients	Maxiumum single dose[*1] (g)		Maximum daily dose [*1] (g)	
			Extracts (amount converted from original crude drug ingredient)	Powders	Extracts (amount converted from original crude drug ingredient)	Powders
A	1	I Crude drug ingredient				
		Frangula bark	1.5	—	3	—
		Pharbitidis semen	—	0.1	—	0.3
		Rhei rhizoma	2	1.5	4	3
		Rosae fructus	1.7	0.67	5	2
		Sennae folium	3	0.75	6	1.5
		Sennae fructus	—	0.75	—	1.5
	Group	Active ingredients	Maxiumum single dose (g)		Maximum daily dose (g)	
	2	Magnesium hydroxide	0.5		2.1	
		Magnesium oxide	0.5		2	
	3	Calcium polycarbophil	1		6	
		Psyllium husk[*3]	3.4		10	
	4	Docusate sodium (Dioctyl sodium sulfosuccinate; DSS)	0.2 (0.12)[*4]		0.2	
Category	Group	Active ingredients	single dose (g)		Maximum daily dose (g)	
B	1	Bisacodyl	0.005－0.01		0.01	
	2	Glycerin	1.5－3		3	
Category	Group	Active ingredients	Maximum daily dose (g) [*1]			
			Extracts (amount converted from original crude drug ingredient)		Powders	
C		Glycyrrhizae radix	5		1.5	
		Moutan cortex	4		1.3	
		Smilacis rhizoma	5		1.5	
D		Cinnamomi cortex	2.5		0.5	
		Coptidis rhizoma	1.5		0.75	
		Foeniculi fructus	1.5		0.5	
		Magnoliae cortex	2.5		0.75	
		Scutellariae radix	3		1.5	

*1. Extract and powder of the same ingredient must not be used together. If there is no maxiumum single dose or there is no maximum daily dose for the extract (or powder), the ingredient must not be used as a extract (or powder) in combination. The Maxiumum single dose or maximum daily dose for an extract is expressed as the amount of the crude drug ingredient used to make the extract.

*2 The amount of maxiumum single dose and maximum daily dose of sennosides are quantified by the calculating the amount of sennoside A, sennoside B or sennoside A & B in the preparation. (excluding salt base).

*3. Psyllium Husk: Includes the husk of *Plantago 45vate* [Blond Psyllium, Indian Psyllium or Ispaghula], *Plantago psyllium* and *Plantago indica* (*Plantago arenaria)* [Spanish or French Psyllium (Fam. Plantaginaceae)].

*4. Wheneveran oral preparation is combined with docusate sodium (dioctyl sodium sulfosuccinate; DSS) in Category A Group 4 or other active ingredients in Category A and the dosage and administration is one time per day, the maxiumum single dose of Docusate Sodium for calculating the combination coefficient of the ingredient listed in Category A Group 4, and the lower limit of the maximum daily dose of using is 0.12g.

II. Combination rules (see Table 2)

(I) Oral preparations:

1. Essential composing ingredients: The active ingredients in Category A Group 1, Group 2, Group 3, and Group 4 of Table 1. The formula of the preparation must contain at least one essential composing ingredient.
2. Optional composing ingredients: The active ingredients in Category C and Category D of Table 1.
3. Unless otherwise stipulated, the aforementioned essential composing ingredients can be used in combination with each other,

and can be used with the optional composing ingredients mentioned above as a compound preparation.

4. Calcium polycarbophil in category A Group 3 of Table 1 is limited to single-ingredient preparation only.
5. Among the active ingredients in Category A Group 1, Sennae Folium or Sennae Fructus cannot be used in combination with Sennosides, but Sennae Folium and Sennae Fructus can be used together.
6. Among the essential composing ingredients, at most four active ingredients in Category A Group 1 can be combined; for the active ingredients in Category A Group 2, Group 3 and Group 4, at most one active ingredient can be combined of each Group. However, overall, at most four essential composing ingredients can be combined at the same time.
7. Among optional composing ingredients, at most three active ingredients in Category C can be combined; and at most four active ingredients in Category D can be combined together at the same time. However, overall, at most five optional composing ingredients can be combined at the same time.
8. Qualitative tests should be carried out for preparations containing crude drug ingredients (Table 1 Category A Group 1 I, Category C and Category D); and quantitative tests should be carried out for crude drug ingredients with indicator ingredients as recorded in the pharmacopoeias.

(II) Suppositories:

1. essential composing ingredients: The active ingredients in Category B Group 1 and Group 2 of Table 1.
2. Single-ingredient preparations only.

Table 2 Combination rules and combination coefficients

Preparations / Active ingredients			Combination rules		Ingredients from the same Category Combined with one ingredient	Combined with at least two ingredients from the same Category		Notes	
			Oral preparations	Suppositories	Combination coefficient	Combination coefficient	The lower limit of the daily maximum dose of each ingredient		
A Category	Group 1	Stimulant laxative	(a) ◎	×	1/2≦≦1	1/2≦≦2	1/5	Can be combined with up to four ingredients.	Up to four ingredients in Category A can be combined together at the same time.
			(b) ◎				1/5		
			I ◎				1/10		
	Group 2	saline laxative					1/5	Can be combined with at most one ingredient.	
	Group 3	Bulk-forming laxative					1/5	Can be combined with at most one ingredient;calcium polycarbophil is a single-ingredient preparations only.	
	Group 4	Stool softener					1/5	Can be combined with at most one ingredient.	
B Category	Group 1	Stimulant laxative Bisacodyl	×	◎	From Table 1			Single-ingredient preparations only.	
	Group 2	Osmotic laxative Glycerin							
C Category	Auxiliary alleviative laxative ingredients		○	×	1/10≦≦1	≦2	1/10	Can be combined with up to three ingredients.	With ingredients from Category C and Category D, up to five ingredients can be combined together at the same time.
D Category	stomach health Ingredients		○	×	1/5≦≦1	1/5≦≦2	The content is not specified.	Can be combined with up to four ingredients.	

◎: Essential composing ingredients ○: Optional composing ingredients ×: Non-composing ingredient.

III. Combination dose of active ingredients (see Table 2)

(I) Oral preparations

1. Ingredients from Table 1 Category A:

(1) The one-time maximum dose and daily maximum dose of each active ingredient must not exceed the maxiumum single dose and maximum daily dose stipulated in Table 1.

(2) When an active ingredient in one Category is composed, the combination coefficient for that category should be between 1 and 1/2.

(3) When two or more active ingredients from the same Category are used in combination, the combination coefficient for that category must be between 2 and 1/2, and whenever the combination ingredients from Category A Group 1 (a), (b) or Category A Group 2, Group 3 or Group 4, the lower limit of the combination coefficient for the daily maximum dose of each composing ingredient in that Group can not be less than 1/5. If the combination ingredients from Category A Group 1 (c), the lower limit for the combination coefficient for the daily maximum dose of each composing ingredient in that Group should not be less than 1/10.

2. When the formula contains an ingredient in Category C of Table 1:

(1) The daily maximum dose for each active ingredient should not exceed the maximum daily dose specified in Table 1. Whenevercombined with ingredients from Category C, the one-time maximum dose for each active ingredient should not exceed 1/3 of the maximum daily dose specified in Table 1.

(2) When an active ingredient in one Category is composed, the combination coefficient for that category should be between 1 and 1/10.

(3) When two or more active ingredients from the same Category are used in combination, the combination coefficient for that Category should not be greater than 2, and the lower limit for the combination coefficient for the daily maximum dose of each composing ingredient in that Category should not be less than 1/10.

3. When the formula contains an ingredient in Category D of Table 1

(1) The daily maximum dose for each active ingredient should not exceed the maximum daily dose specified in Table 1. Whenevercombined with ingredients from Category C, the one-time maximum dose for each active ingredient should not exceed 1/3 of the maximum daily dose specified in Table 1.

(2) When an active ingredient in one Category is composed, the combination coefficient for that category should be between 1 and 1/5.

(3) When two or more active ingredients from the same Category are combined, the combination coefficient for that Category should be between 2 and 1/5.

4. Three methods are available for calculating the combination coefficient for each ingredient in Category A, based on dosage and administration:

(1) Once a day:

The daily maximum dose of the composing ingredient divided by the maxiumum single dose of that ingredient.

(2) Once to twice a day:

The daily maximum dose of the composing ingredient divided

by the maxiumum single dose of that ingredient and multiplied by 2, or the maximum daily dose of that ingredient, whichever is smaller.

(3) One to three times a day:

The daily maximum dose of the composing ingredient divided by the maximum daily dose of that ingredient.

Combination coefficients $= \Sigma(X_i/mX_i)$

$= (X_1 / mX_1)+(X_2 / mX_2)+\ldots\ldots+(X_n / mX_n)$

X_i: Daily maximum dose of the composing ingredient i from each Category

mX_i: maximum daily dose of the composing ingredient i from each Category.
(Or the maxiumum single dose, or the maxiumum single dose multiplied by 2, depending on dosage and administration.)

n: Number of composing ingredients in each Category.

5.Calculation of k value (daily dose range):

k value needs to be added to the calculation for different dosage and administration of the laxatives, in order to confirm whether the range of daily maximum and minimum doses is appropriate.

K = Daily maximum dose of composing ingredient/daily minimum dose of composing ingredient

Acceptable range of k value is $1 < k \leqq 4$

6. The calculation of combination coefficient for each ingredient in Category C and Category D:

Combination coefficients $= \Sigma(X_i/mX_i)$

$= (X_1 / mX_1)+(X_2 / mX_2)+\ldots\ldots+(X_n / mX_n)$

X_i: Daily maximum dose of the composing ingredient i from each Category

mX_i: The maximum daily dose of the composing ingredient i from each Category.

N: Number of composing ingredients in each Category.

(II) Suppositories:

1. The upper and lower limits for the single dose and the maximum daily dose for each ingredient in Category B Group 1 and Group 2 are stipulated in Table 1.
2. Calculation of combination coefficient and k value is not required.

C. Dosage form

I. Limited to tablets, film coated tablets, sugar coated tablets, capsules, soft capsules, pills, oral solutions, powders, granules for internal use, and fine granules only.

II. Oral solutions can only contain saline laxatives from Category A Group 2.

III. Oral preparations containing bisacodyl from Category A Group 1 (a) can only be enteric coated dosage form.

IV. Preparations containing bisacodyl from Category B Group 1 and glycerin from Category B Group 2 can be suppositories.

I. Use (indications)

To soften stool. If the combination ingredients contain stimulant laxatives from Category A Group 1, the indication can be to relieve constipation.

E. Precautions

I. Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product.

(II)People with gastrointestinal obstruction, abdominal pain, vomiting, or nausea.

(Must be indicated for preparations containing stimulant laxatives in Table 1 Category A Group 1 and Category B Group 1, saline laxatives in Table 1 Category A Group 2, or osmotic laxatives in Table 1 Category B Group 2.)

(III)People with gastrointestinal obstructions, abdominal pain, vomiting, nausea, intestinal ulcers, stenosis, or adhesion.

(Must be indicated for preparations containing bulk-forming laxative in Table 1 Category A Group 3 or stool softeners in Table 1 Category A Group 4.)

(IV) People who have limit of their water intake.

(Must be indicated for preparations containing bulk-forming laxatives in Table 1 Category A Group 3.)

II.Under the following conditions, consult your doctor before use:

(I) Children under the age of 3 years.

(II) People with kidney dysfunction.

(Must be indicated for preparations containing saline laxatives in Table 1 Category A Group 2.)

(III)Adults aged 65 years and over, or with severe abdominal pain, nausea, vomiting, edema and hypertension, cardiac dysfunction, or kidney dysfunction.

[Must be indicated for preparations containing more than 1g Glycyrrhizae radix from Table 1 Category C (or more than 1g of the original crude drug ingredient for extract).]

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Pregnant women, women who might be pregnant, or breastfeeding women.

(II) Having taken the preparations for more than one week.

(III) Use with other laxatives.

IV. Other

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III) Do not exceed the stated dose.

(IV) Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose.
(Must be indicated for solutions.)

(V) Applied to the anus only. If the medicine is deformed because it is too soft, do not use.
(Must be indicated for suppositories.)

(VI) Please wait a while until there is a continued intense feeling to defecate. If you defecate immediately after using this medicine, you should completely eliminate the medicine, rendering it ineffective.
(Must be indicated for suppositories.)

(VII) This medicine should not be used for a long tearm. Once bowel movement is normal, discontinue use. Try to improve constipation with a fiber-rich diet, sufficient water intake and exercise.

(VIII) Diarrhea might occur while using this medicine.

(IX) Long-term use can cause electrolyte imbalance and dehydrated.
(Must be indicated for preparations containing stimulant laxatives in Table 1 Category A Group 1 and Category B Group 1, saline

laxatives in Table 1 Category A Group 2 or stool softener in Table 1 Category A Group 4.)

(X) Must be swallowed in whole, not chewed or ground; do not ingest antacids or milk one hour before and after taking this medicine. (Must be indicated for oral preparations containing Bisacodyl)

(XI) Use will turn acidic urine yellow or brown, and alkaline urine pink or fuchsia. It also can cause the darkening of the colonic mucosa. (Must be indicated for preparations containing the group of senna.)

(XII) While using the preparation in large quantities will cause congestion of organs in the pelvic cavity. Pregnant women, women in menstruation and people with nephritis or hemorrhoids must be careful using.
(Must be indicated for preparations containing aloe.)

(XIII) Taking 12 hours to three days to take effect.
(Must be indicated for preparations containing bulk-forming laxatives from Table 1 Category A Group 3.)

(XIV) Take the medicine with sufficient water, according to the instructions; otherwise, it might cause esophageal obstruction, such as chest pain, vomiting, excessive saliva or choking.
(Must be indicated for preparations containing bulk-forming laxatives in Table 1 Category A Group 3.)

(XV) This medicine cannot be used with mineral oil.
(Must be indicated for the preparations containing stool softener in Table 1 Category A Group 4.)

F. Dosage and Administration

I. Oral preparations

Adults and 12 years of age and over.	(a) Once a day ,and ◯－◯ each time, take it before

	bedtime (or empty stomach). (b) once to twice a day and ◯－◯ each time, take it in the morning and evening (the interval must be 4 hours or more), on empty stomach (or with meals). Do not exceed twice a day. © 1—3 times a day, ◯－◯ each time, take it before meals (or with meals). Do not exceed three times a day; interval between uses must be 4 hours or more. For the three methods above, "use the minimum dose for the first time, and adjust the dose depending on conditions."
Children 6 to less than 12 years of age.	1/2 of adult dosage.
Children 3 to less than 6 years of age.	1/4 of adult dosage.
Children under the age of 3 years.	Consult your doctor.

* Take at least 240ml of water when using the drug.
(Must be indicated for preparations containing bulk-forming laxative in Category A Group 3.)

Ⅱ.Suppositories

Use one dose each time. Additional one dose may be used if the symptom has not been relieved. Up to ◯ dose can be used per day. The drug cannot be halved. (The age group: consult the oral preparation .)

G. Warnings

I. After useing the medicine, if any of the following side effects occured, please stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

(I) The following information must be indicated for oral preparations:

Body part	Side effects
Gastrointestinal tract	Nausea, vomiting, and severe abdominal pain.
Other	Allergic symptoms such as rash.

(II) The following information must be indicated for preparations containing the group of senna, or Rhei rhizoma:

Body part	Side effects
Other	Allergic symptoms, such as red or itchy skin.

(III) The following information must be indicated for suppository preparations:

Body part	Side effects
Gastrointestinal tract	Rectal irritation and abdominal discomfort.

II. After useing the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Any discomfort occurs.

(II) Persistent diarrhea or even worse.

(III)Bloody stools or spontaneous intestinal bleeding.

(IV)No effect after one week of use.

(V) A decrease in urinary output, swelling of the face or hands and feet, heavy eyelids, stiff hands, elevated blood pressure or headache while using the medication. [Must be indicated for preparations containing more than 1g Glycyrrhizae radix from Table 1 Category C (or more than 1g of the original crude drug ingredient for extract).]

Gastrointestinal drug products

A. Scope

I. This guideline applies to oral products for the neutralizing stomach acidity, improving gastrointestinal health, improving digestion, antidiarrheals, and preventing flatulence.

II. This guideline does not apply to preparations made only from crude drug ingredients listed in this set of guidelines.

B. Active ingredients

I. Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the maximum daily dose or minimum daily dose for each active ingredient.

Table 1. Active ingredient and dose

Category	Group	Active ingredients	Maximum daily dose (g)
A. Acidity neutralization	1	(a) Aluminum	
		Aluminum hydroxide (Hexitol)	3.8
		Aluminum hydroxide dried gel (Dried aluminum hydroxide)	3.0
		Aluminum hydroxide gel (4% w/v Aluminum oxide)	30ml (Equivalent to 1.2g aluminum oxide)
		Aluminum phosphate	8.0
		Synthetic aluminum silicate	10.0
		Dihydroxyaluminum sodium carbonate (Basic aluminum carbonate)	2.0
		(b) Aluminum & Magnesium	
		Aluminum hydroxide-magnesium carbonate co-dried gel	3.0
		Aluminum hydroxide-magnesium carbonate-calcium carbonate co-ppt	4.0
		Aluminum magnesium metasilicate	4.0

Table 1. Active ingredient and dose (continued)

Category	Group	Active ingredients	Maximum daily dose (g)	
A. Acidity neutralization	1	Aluminum magnesium silicate (Magnesium alumino silicate) (Almasilate)	4.0	
		Hydrotalcite (Aluminum magnesium carbonate hydroxide hydrate)	4.0	
		Magaldrate (Aluminum magnesium hydroxide sulfate)	4.0	
		(c) Magnesium		
		Magnesium carbonate	2.0	
		Magnesium hydroxide	1.5	
		Magnesium oxide	1.0	
		Magnesium trisilicate (Magnesium silicate)	6.0	
		(d) Calcium		
		Calcium carbonate	3.0	
		Calcium phosphate, dibasic	3.0	
		(e) Sodium		
		Aluminum hydroxide-sodium bicarbonate co-ppt	2.0	
		Sodium bicacbonate	5.0	
	2	Aminoacetic acid (Glycine)	0.9	
		Dihydroxyaluminum aminoacetate (Aluminum glycinate)	3.0	
Category	Group	Active ingredients	Maximum daily dose (g) [*1]	
			Extracts (amount converted from original crude drug ingredient)	Powders
B.Stomach health	1	*Acorus calamus* rhizoma	6.0	2.0
		Aloe	—	0.15
		Alpinia officinarum rhizoma	3.0	1.0
		Amomi semen	3.0	1.0
		Animal bile (not including Fel ursi)	—	0.5
		Anisi 59hizome59 fructus	3.0	1.0
		Atractylodis lanceae rhizoma	5.0	2.0
		Atractylodis rhizoma	5.0	2.0
		Aurantii pericarpium	5.0	3.0
		Calumbae radix	5.0	1.5
		Capsici fructus	—	0.1
		Cardamomi fructus	3.0	1.0
		Caryophylli flos	2.0	0.5
		Cinnamomi cortex	5.0	1.0
		Coptidis rhizoma	3.0	1.5

Table 1. Active ingredient and dose (continued)

Category	Group	Active ingredients	Maximum daily dose (g) [*1]	
			Extracts (amount converted from original crude drug ingredient)	Powders
B. Stomach health	1	Curcumae rhizoma	6.0	2.0
		Foeniculi fructus	3.0	1.0
		Gentianae radix	1.5	0.5
		Gentianae scabrae radix	1.5	0.5
		Ginseng radix	6.0	3.0
		Lupli strobilus (hops)	3.0	1.0
		Magnoliae cortex	5.0	1.5
		Myristicae semen	3.0	1.0
		Phellodendri cortex	3.0	3.0
		Picrasmae lignum	5.0	0.5
		Piperis fructus	5.0	1.5
		Piperis nigri fructus	5.0	1.5
		Rhei rhizoma	0.2	0.1
		Saussureae radix	3.0	1.0
		Scutellariae radix	6.0	3.0
		Swertiae herba	1.5	0.05
		Trifolic 60hizom folium	4.0	1.3
		Zanthoxyli fructus	3.0	1.0
		Zedoariae rhizoma	3.0	3.0
		Zingiberis rhizoma	3.0	1.0
		Active ingredients	Maximum daily dose (g)	
		Anise oil	0.03	
		Cinnamon oil	0.03	
		Clove oil	0.02	
		Fennel oil	0.08	
		Ginger oil	0.03	
		Mentha oil (peppermint oil)	0.03	
		Nutmeg oil	0.09	
		Orange peel oil	0.03	
	2	l-Menthol	0.18	
	3	Carnitine chloride	0.6	
	4	Dried yeast	10.0	

Table 1. Active ingredient and dose (continued)

Category	Group	Active ingredients	Maximum daily dose (g)
C. Digestion	1	(a)Pancreatic enzymes	1. The lipase digestive ability contained in each unit of the product should not exceed 20,000 USP, or EP, BP, FIP units[*2]. (The unit dosage form dose must be expressed in terms of "weight.") 2.For other digestive enzymes, the basis of the stated function of "improving digestion" from formulation basis or relevant pharmacopoeias must be attached, and the digestive unit must be consistent with the basis of formulation basis (USP unit, BP unit, JP unit, EP unit, FIP unit, etc.)[*3] (The unit dosage form dose must be expressed in terms of "weight.")
		Pancreatin	
		Pancrelipase	
		(b) Other digestive enzymes	
		Beta-galactosidase	
		Fat digestive enzyme	
		Protein digestive enzyme	
		Starch digestive enzyme	
		Cellulose digestive enzyme	
	Group	Active ingredients	Maximum daily dose (g)
	2	Bile extract (powder)	0.5 (1.5)
		Cholic acid	0.9
		Dehydrocholic acid	0.5
		Oxycholanates (salts of oxycholic acid)	0.15
		Ursodesoxycholic acid	0.06
Category	Group	Active ingredients	Minimum daily dose
D. Intestinal health	1	Bacillus butyricus	1×10^6 (The unit dosage form dose must be expressed in terms of "weight.")
		Bacillus coagulans	
		Bacillus mesentericus	
		Bacillus polyfermenticus	
		Bacillus subtilis (Bacillus natto)	
		Bifidobacterium[*4]	
		Clostridium butyricum	
		Lactobacillus acidophilus	
		Lactobacillus bulgaricus	
		Lactobacillus casei	
		Lactobacillus lactis	
		Lactobacillus rhamnosus	

Table 1. Active ingredient and dose (continued)

Category	Group	Active ingredients	Maximum daily dose (g)[*1]	
			Extracts (amount converted from original crude drug ingredient)	Powders
D	2	Gambir	—	2.0
		Geranii herba	10.0	3.0
Category	Group	Active ingredients	Maximum daily dose (g)	
E. Anti-diarrheals	1	Berberine chloride	0.3	
		Berberine tannate	0.3	
		Creosote	0.5	
		Guaiacol (carbonate)	0.6 (1.2)	
	2	Albumin tannate	4.0	
	3	Aluminum hydroxide naphthoate	0.9	
		Natural aluminum silicate	10.0	
		Kaolin	10.0	
		Medicinal carbon	5.0 (2.0) [*5]	
		Pectin	0.6	
	4	Calcium lactate	5.0	
	5	Attapulgite	9.0	
		Calcium polycarbophil	6.0	
	Group	Active ingredients	Maximum daily dose (g) [*1]	
			Extracts (amount converted from original crude drug ingredient)	Powders
	6	Coptidis rhizoma	3.0	1.5
		△ Gambir	—	2.0
		△ Geranii herba	10.0	3.0
		Phellodendri cortex	9.0	3.0
		Sophorae radix	3.0	1.5
		Swertiae herba	—	0.9
Category	Group	Active ingredients	Maximum daily dose (g)	
F. Anti-flatulence		Dimethicone (Dimethylpolysiloxane)	0.5	
		Simethicone (=Activated dimethicone)	0.5	
G. Local anesthesia		Oxethazaine	0.08	
H. Other		Belladonna extract	0.03	
		Scopolia extract	0.03	

*1. Extract and powder of the same ingredient must not be used at the same time. If there is no Maximum daily dose for the extract Category, the ingredient should not be used as extract. The Maximum daily dose for an extract is expressed as the amount of the original crude drug ingredient used to make the extract.

*2. For products containing Lipase (pancreatic enzymes and other lipase), the lipase digestive ability contained in each unit of the product (Maxiumum single dose ability) should not exceed 20,000 USP or EP, BP, FIP unit[*2]. For Japanese products, the permit or related evidence for using in the OTC drugs in Japan should be submitted.

3. For other digestive enzymes, the basis of the stated function of "improving digestion" from formulation basis or relevant pharmacopoeias must be attached, and the digestive unit must be consistent with the formulation basis (USP unit, BP unit, JP unit, EP unit, FIP unit, etc.).

*4. For the use of microorganisms of *Bifidobacterium* genus in Category D (intestinal health), the permit or related evidence for using in the OTC drugs in domestic or abroad should be submitted.

*5. Whenever calculating the lower limit of combination coefficient and the daily dose for preparations containing Medicinal carbon in Category E Group 3, the Maximum daily dose used is 2.0g.

II.Combination rules:

(I)Essential composing ingredients and optional composing ingredients (see Table 2):

1.The essential composing ingredients and optional composing ingredients for various gastrointestinal preparations are stipulated in Table 2.

2.For anti-acids, stomach health preparations, digestant preparations, intestinal health preparations and antidiarrheal preparations, the formula must contain at least one essential composing ingredient.

3. The formula for a common gastrointestinal drug product must contain at least two types of active ingredients in Category A (antiacid), Category B (Stomach health), Category C (digestant) or Category D Group 1 (intestinal viable bacteria) as the essential composing ingredients.

(II)Combination rules for each ingredient (see Table 2):

1.The following ingredients are limited to single-ingredient preparation only.

(1)Beta-galactosidase and pancrelipase in Category C Group 1 of Table 1.

(2)*Bacillus coagulans*, *Bacillus mesentericus*, *Lactobacillus lactis* and *Lactobacillus rhamnosus* in Category D Group 1 of Table 1.

(3)Attapulgite and calcium polycarbophil in Category E Group 5 of Table 1.

2. Carnitine chloride in Category B Group 3 of Table 1 cannot be used in combination with the ingredients in Category H.

3. Pancreatin in Category C Group 1 of Table 1 cannot be used in combination with pepsin.

4. Berberine chloride and berberine tannate in Category E Group 1 of Table 1 cannot be used in combination with Phellodendri cortex or Coptidis 65hizome.
5. Only the antidiarrheal crude drug ingredients marked with "△" in Category E Group 6 of Table 1 can be combined with stomach health preparations, digestant preparations, intestinal health preparations or common gastrointestinal medicines.
6. The anti-flatulence ingredients from Category F can be used as single-ingredient preparation, or can be used as compound preparations in accordance with the combination rules in Table 2 (at most one ingredient in Category F can be combined).
7. The local anesthetic ingredients in Category G can be used as single-ingredient preparation, or combined only with anti-acid ingredients in Category A of Table 1 as compound preparations (ingredients in Category A can be used as optional composing ingredients).
8. At most one ingredient in Category H can be combined.

(III) Antiacid:

1. Antiacid preparations must indicate the acid neutralizing capacity of a single dose in terms of mEq.
2. Antiacids can be combined with laxatives (and must meet the stipulations for the type and combination dose of ingredients in the laxative guideline) to prevent the side effect of constipation, but should not claim a laxative effect.

(IV) When preparations contain magnesium-containing antiacids in Category A Group 1 (b) and (c) of Table 1, the magnesium content, as mEq, of a single dose must be indicated.

(V) If the sodium content of a single dose is above 0.2 mEq (5 mg), the sodium content, as mEq, of a single dose must be indicated.

(VI)Qualitative tests shall be carried out for preparations containing crude drug ingredients (Category B Group 1, Category D Group 2 and Category E Group 6 of Table 1); and quantitative tests shall be carried out for crude drug ingredients with indicator ingredients that are acting as the essential composing ingredients as written in pharmacopoeias or official specifications and standards.

III. Combination dose of active ingredients (see Table 3):

(I) Except for the digestive enzyme ingredients in Category C Group 1 of Table 1 and intestinal viable bacteria ingredients in Category D Group 1, the daily maximum dose of each ingredient should not exceed the Maximum daily dose stipulated in the table; the Maximum single dose is 1/3 of the Maximum daily dose.

(II) When the formula contains a digestive enzyme in Category C Group 1 of Table 1, the combination dose for each combination ingredient from that Group must meet the stipulations in the notes in Table 1.

(III) When the formula contains intestinal viable bacteria in Category D Group 1 of Table 1, the Minimum single dose must be 1/3 of the Minimum daily dose for that Group stipulated in Table 1.

(IV) The pharmacological action of the ingredients in the same category has additive effects. Whenever two or more ingredients are combined, the safety of such must be considered, and such use must meet the stipulations for combination coefficients in Table 3.

(V) Formulas containing antiacids in Category A of Table 1:

1. When the formula contains one active ingredient in Category A, the combination coefficient for that category should not be greater than 1; two or more active ingredients are combined, the combination coefficient should not be greater than 2.

2. When ingredients in Category A are used as essential composing ingredients, the consumption of 0.1N HCL of the daily dose of the preparation should not be less than 150 mL; and when such ingredients are used as optional composing ingredients, it should not be less than 75 mL.
3. When an ingredient in Category A is not combination as an active ingredient, the combination coefficient for that ingredient must be less than 1/5 (i.e., the ratio of the daily dose to the Maximum daily dose must be less than 1/5); if it was not less than 1/5, the consumption of 0.1N HCL of the daily dose for the preparation must be less than 75 mL.
4. Combination coefficients $= \Sigma (X_i/mX_i)$
   $= (X_1 / mX_1)+(X_2 / mX_2)+\ldots\ldots+(X_n / mX_n)$
   X_i: Daily dose of the combination ingredient i from Category A.
   mX_i: Maximum daily dose for the combination ingredient i from Category A.
   n: Number of combination ingredients in Category A.

(VI) When the formula contains ingredients in Category B Group 1 or Group 2 of Table 1:

1. When the formula contains any active ingredient in Category B Group 1 or Group 2, the combination coefficient should not be greater than 1; the formula contains any two of the active ingredients in Category B Group 1 or Group 2 (n=2), the combination coefficient should not be greater than 2; the formula contains three or more active ingredients ($n \geqq 3$), the combination coefficient should not be greater than 3.
2. When the ingredients in Category B Group 1 and Group 2 are used as essential composing ingredients, the combination coefficient for these two Groups should not be less than 1/2; when they are used as

the optional composing ingredients, the combination coefficients should not be less than 1/10.

3. Whenever the ingredients in Category B Group 1 and Group 2 are not used as an active ingredient, the combination coefficients for that ingredient must be less than 1/10 (i.e., the ratio of the daily dose to the Maximum daily dose must be less than 1/10).

4. Combination coefficients $= \sum_{i=1} (X_i/mX_i)$

$= (X_1 / mX_1)+(X_2 / mX_2)+\ldots\ldots+(X_n / mX_n)$

X_i: Daily dose of combination ingredient i from Category B Group 1 or Group 2

mX_i: Maximum daily dose for combination ingredient i from Category B Group 1 and Group 2

n: Number of combination ingredients in Table 1 Category B Group 1 and Group 2.

(VII)When the formula contains ingredients in Category B Group 3, Group 4, Category C Group 2, Category D Group 2 or Category E Group 1, Group 2, Group 3, Group 4, or Group 6 of Table 1:

1. When any of the above ingredients are combined and the ingredient from that Group is used as an essential composing ingredient, the combination coefficient for that Group should not be less than 1/2.

2. When any of the ingredients from Category B Group 3 Group 4, Category C Group 2, or Category E Group 1, Group 2, Group 3 or Group 4 is combined, the combination coefficient for that Group should not be greater than 1; If the ingredient is used as an optional composing ingredient, the combination coefficient for that Group should not be less than n/5 (n: number of combination ingredients in the same Group).

3.For ingredients in Category D Group 2 or Category E Group 6, when combined with one ingredient from the same Group, the

combination coefficient for that Group should not be greater than 1; when two or more ingredients are combined, the combination coefficient for that Group should not be greater than 2. If the combination ingredients in Category D Group 2 or Category E Group 6 are used as optional composing ingredients, the combination coefficient for that Group should not be less than n/10 (n: number of combination ingredients in the same Group).

4. Combination coefficients $= \sum_{i=1}^{n} (X_i/mX_i)$
   $= (X_1 / mX_1)+(X_2 / mX_2)+\ldots\ldots+(X_n / mX_n)$
   X_i: Daily dose of combination ingredient i in Group X specified in (VII).
   mX_i: Maximum daily dose for the combination ingredient i in Group X.
   n: Number of combination ingredients in Group X.
5. For ingredients in Category C Group 2, or Category E Group 1, Group 2, Group 3 or Group 4, when two or more ingredients in the same Group are combined, the lower limit for the daily dose for each combination ingredient in the Group is 1/5 of the Maximum daily dose for that ingredient specified in Table 1. For ingredients in Category D Group 2 or Category E Group 6, when two or more ingredients in the same Group are combined, the lower limit for the daily dose for each combination ingredient in the Group is 1/10 of the Maximum daily dose for that ingredient specified in Table 1.

(VIII) When a digestive enzyme in Category C Group 1 of Table 1 is used as the essential composing ingredient in a preparation, the potency of the digestive power for the preparation's daily dose must follow the combination amount for the digestive ability stipulated in the formulation basis or relevant pharmacopoeias; whenever it is used as an optional composing ingredient, the potency of the

digesting capability for the daily dose of the preparation should not be less than 1/2 of the combination amount for the digestive ability stipulated in the formulation basis or relevant pharmacopoeias.

(IX) When intestinal viable bacteria in Category D Group 1 of Table 1 are combined, the number of bacteria contained in the daily dose of the preparation should not be less than 1×10^6.

(X) When ingredients in Category F, Category G or Category H of Table 1 are combined, the combination coefficient for that category should not be greater than 1 and should not be less than 1/5.

Combination coefficient = X/mX

X: Daily dose of combination ingredient x in Category F (or G or H).

mX:The Maximum daily dose for combination ingredient x in Category F (or G or H).

IV. Optional composing vitamins:

(I) Active ingredient and dose that can be combined:

Table 4 stipulates the types of optional composing vitamins, the Maximum daily dose, and the active ingredients.

Table 4. Types of optional composing vitamins

Category	Group	Type		Maximum daily dose
I. Vitamins	1	Vitamin B_1		30mg
		Active ingredients	Bisbentiamine Bisibutiamine Cetotiamine hydrochloride Cycotiamine Dibenzoyl thiamine Dibenzoyl thiamine hydrochloride Fursultiamine hydrochloride Octotiamine Prosultiamine Thiamine hydrochloride (Vitamin B_1) Thiamine mononitrate Thiamine dicetylsulfate Thiamine disulfide	
	2	Vitamin B_2		10mg
		Active ingredients	Riboflavin (Vitamin B_2) Riboflavin butyrate Riboflavin sodium phosphate	
	3	Vitamin B_6		50mg
		Active ingredients	Pyridoxine hydrochloride (Vitamin B_6)	
	4	Vitamin C		500mg
		Active ingredients	Ascorbic acid (Vitamin C) L-Ascorbyl palmitate L-Ascorbyl stearate Calcium ascorbate Sodium ascorbate	
	5	Nicotinamide		27mg
	6	Calcium pantothenate		30mg
	7	Biotin		25mcg

(II) Combination rules and combination dose (see Table 5):

1. When the ingredients from Table 1 Category B (stomach health preparations) or the ingredients in Category C (digestants) are used as essential composing ingredients in a preparation, the preparation can be combined with the active ingredients of Table 4 Category I Group 1 (vitamin B_1).
2. When the ingredients from Table 1 Category D Group 1 (intestinal viable bacteria) are used as essential composing ingredients in a preparation, the preparation can be combined with the active ingredients from Table 4 Category I Groups 1, 2, 3 and 4 (vitamin B_1, vitamin B_2, vitamin B_6 and vitamin C) and Group 6 (calcium pantothenate); If the essential composing ingredients of the preparation contain lactic acid bacteria or lactic acid-producing bacteria in Category D Group 1, they can be combined with nicotinamide (Category I Group 5) and biotin (Category I Group 7). (Certified documents of lactic acid bacteria or lactic acid-producing bacteria must be submitted.)
3. When the ingredients from Table 1 Category E (antidiarrheal preparations) are used as essential composing ingredients in a preparation, the preparation can be combined with the active ingredients from Table 4 Category I Group 1 and Group 2 (vitamin B_1 and B_2).
4. For Table 4 Category I, Groups 1, 2, 3, 4, 5, 6 and 7, the combination coefficient for each Group should not be greater than 1. In other words, the sum of the ratio of daily dose to the Maximum daily dose of each combination ingredient should not be greater than 1 in the same Group.

Table 5 Combination rules and combination coefficients

Category	Group	Types of vitamins that can be combined	Essential composing ingredients in preparations				Combination coefficient	Notes
			Category B	Category C	Category D Group 1	Category E		
I	1	Vitamin B_1	○	○	○	○	≦1	
	2	Vitamin B_2			○	○	≦1	
	3	Vitamin B_6			○		≦1	
	4	Vitamin C			○		≦1	
	5	Nicotinamide			○		≦1	Can only be combined when lactic acid bacteria or lactic acid-producing bacteria are used as an essential composing ingredient.
	6	Calcium pantothenate			○		≦1	
	7	Biotin			○		≦1	Can only be combined when lactic acid bacteria or lactic acid-producing bacteria are used as an essential composing ingredient.

○: Vitamins that can be combined

C. Dosage form

I. Limited to tablets, chewable tablets, film coated tablets, sugar coated tablets, capsules, soft capsules, pills, oral solutions, syrups, suspension solutions, drops, powders, powders for solution, powders for syrup, powders for suspension solutions, powders for drops, granules for internal use, granules for syrups, granules for suspension solutions and fine granules.

II. The preparations containing the digestive enzymes in Category C Group 1 of Table 1 as active ingredients can be enteric coated dosage forms.

D. Use (indications)

I. If the preparation contains active ingredients from any category in Table 1 as essential composing ingredients, the indications from the corresponding category in Table 6 can be indicated.

II. If active ingredients from at least two categories in Table 1 Category A, Category B, Category C or Category D are used as essential composing ingredients in common gastrointestinal drug products, the indications can be indicated together.

III. If the preparation contains anti-flatulence ingredients from Table 1 Category F, the indications can be indicated together.

IV. For preparations containing local anesthetic ingredients from Table 1 Category G, the indications are as those shown in Table 6 Category G.

Table 6 Use (indications)

Category	Essential composing ingredients (◎)	Use (indications)
A	Acidity neutralization	Relief of upset stomach or heart burn, or hyperacidity being diagonosed as the symptom accompanied with stomach ulcer, duodenal ulcer, gastritis or esophagitis.
B	Stomach health	Loss of appetite, swelling of the stomach or abdomen, indigestion.
C	Digestion[*6]	To help digestion.
D	Intestinal health	Relief of mild diarrhea, abdominal pain or constipation, improving intestinal functions (adjustment of bowel movements), softening stools.
E	Antidiarrheals	Relief of mild or moderate acute diarrhea.
F	Anti-flatulence	Reduce flatulence and symptoms related to flatulence.

G	Local anesthesia	Relief of the stomach pain, hyperacidity, and stomach discomfort or heart burn associated with gastritis, enteritis or esophagitis.

*6. The use (indication) of beta-galactosidase in Category C Group 1 of Table 1is: To alleviate all types of diarrhea caused by lactose intolerance.

E. Precautions, dosage and administration, and warnings for the use of acidity neutralization ingredients (Table 1 Category A)

[**Precautions]**

I. Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product.

II. Under the following conditions, consult your doctor before use:

(I) Children under the age of 3 years.

(II) People with digestive tract ulcers.

(III)People with kidney diseases

(Must be indicated for the preparations containing magnesium greater than 50mEq (0.6g) in maximum stated daily dose.)

(IV) People who are required to limit dietary salt intake

(Must be indicated for preparations containing sodium greater than 5mEq (0.115g) in maximum stated daily dose.)

(V) People with high blood pressure, heart disease, kidney disease, ascites or edema.

(Must be indicated for preparations containing sodium bicarbonate.)

(VI) Patients with renal failure (long-term use of gastric drugs containing aluminum might cause or aggravate dialysis osteomalacia, dialysis-induced brain diseases and hypophosphatemia caused by dialysis treatment. Use with caution.)

(Must be indicated for preparations containing aluminum antiacids.)

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Pregnant women, women who might be pregnant or breastfeeding women.

(II) Whenever used in combination with other drugs.

(III) People with low tolerance to milk or dairy food.

(Must be indicated for the excipients of the preparation containing lactose, and the amount of lactose of the daily maximum recommended dosage is greater than 5g.)

IV. Others :

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III) Do not exceed the stated dose.

(IV) Do not take more than the maximum daily dose in one day, or continuously take the maximum daily dose for more than two weeks.

(V) People taking the medicine with calcium milk in a long term will cause hypercalcemia, renal failure, alkalosis, nausea, vomiting, headache, unconsciousness, anorexia, etc.

(Must be indicated for the preparations containing sodium bicarbonate.)

(VI) Patients with kidney disease taking a high dose will result in alkalosis; high blood pressure, heart failure, kidney failure, edema, ascites will be aggravated.

(Must be indicated for the preparations containing sodium bicarbonate).

(VII) The preparation might cause bloating and burping.

(Must be indicated for the preparations containing carbonate (or bicarbonate))

(VIII) Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose.

(Must be indicated for the solution.)

(IX) The tablets must be chewed or melted in the mouth before swallowing.

(Must be indicated for the chewable tablet.)

(X) Antiacid tablets should be chewed before being swallowed.
(Must be indicated for the tablet.)

[Dosage and Administration]

Age	Dose
Adults and 12 years of age and over.	Three to four times a day or when needed.
Children 6 to less than 12 years of age.	1/2 of adult dosage.
Children 3 to less than 6 years of age.	1/4 of adult dosage.
Children under the age of 3 years.	Consult your doctor.

[Warnings]

I. After taking the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

Body part	Side effects
Gastrointestinal tract	Constipation[1], nausea[1], vomiting[1], diarrhea[2,3]

1 Must be indicated for antiacids containing aluminum.

2 Must be indicated for antiacids containing magnesium.

3 Must be indicated for antiacids containing calcium.

II. After taking the medicine, if any of the following symptoms occured, please stop using it immediately, and seek the medical advice:

(I) Any discomfort occurs.

(II) If symptoms are not improved after taking this medicine for several days.

F. Precautions, dosage, administration, and warnings for the use of ingredients for stomach health (Table 1 Category B).

[Precautions]

I. Do not use in the following conditions:

(I)People who are allergic to the ingredient(s) of this product.

II. Under the following conditions, consult your doctor before use:

(I) Children under the age of 3 years.

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Pregnant women, women who might be pregnant or breastfeeding women.

IV. Others:

(I)Store properly to prevent children from accidentally taking this drug.

(II)Avoid direct sunlight.

(III)Do not exceed the stated dose.

(IV)Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose.
(Must be indicated for solutions.)

(V)The tablets must be chewed or melted in the mouth before swallowing.
(Must be indicated for the chewable tablet.)

[Dosage and Administration]

Age	Dose
Adults and 12 years of age and over.	1 adult dosage, three to four times a day or when needed.
Children 6 to less than 12 years of age.	1/2 of adult dosage.

Children 3 to less than 6 years of age.	1/4 of adult dosage.
Children under the age of 3 years.	Consult your doctor.

[Warnings]

I. After taking the preparation, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Any discomfort occurs.

(II)If symptoms are not improved after taking this medicine for several days.

G. Precautions, dosage and administration, and warnings for the use of digestive enzymes (Table 1 Category C)

[Precautions]

I. Do not use in the following conditions:

(I)People who are allergic to the ingredient(s) of this product.

II. Under the following conditions, consult your doctor before use:

(I) Children under the age of 3 years.

(II)Children under the age of 12 years.

(Must be indicated for preparations containing pancrelipase from Table 1 Category C Group 1 (a) pancreatic enzymes).

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I)Pregnant women, women who might be pregnant or breastfeeding women.

(II)People with low tolerance to milk or dairy food.

(Must be indicated for the excipients of the preparation containing lactose, and the amount of lactose of the daily maximum recommended dosage is greater than 5g.)

IV. Others:

(I) Store properly to prevent children from accidentally taking this drug.

(II)Avoid direct sunlight.

(III)Do not exceed the stated dose.

(IV)Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose.

(Must be indicated for solutions.)

(V) Drug must be swallowed whole and must not be halved or chewed.

(Must be indicated for enteric coated preparations.)

[Dosage and Administration]

I. Digestant preparations

Age	Dose
Adults and 12 years of age and over.	1 adult dosage, Three to four times a day or when needed.
Children 6 to less than 12 years of age.	1/2 of adult dosage.
Children 3 to less than 6 years of age.	1/4 of adult dosage.
Children under the age of 3 years.	Consult your doctor.

II. Preparations containing pancrelipase listed in Table 1 Category C Group 1 (a) pancreatic enzymes:

Age	Dose
Adults and 12 years of age and over.	Three times a day. Take with a meal and plenty of water. Do not take without food.
Children under the age of 12 years.	Consult your doctor.

[Warnings]

I. After taking the preparation, if any of the following side effects occured please stop using it immediately, and bring the insert to consult your doctor, pharmacist or assistant pharmacist.

(I) The following information must be indicated for preparations containing digestive enzymes (Table 1 Category C Group 1):

Body part	Side effects
Other	Having an allergy sometimes

II. After taking the preparation, if any of the following symptoms occured, please stop using it immediately, and seek medical advice:

(I)Any discomfort occurs.

(II)If symptoms are not improved after taking this medicine for several days.

(III)The following information must be indicated for preparations containing pancreatic enzymes:

Body part	Side effects
Gastrointestinal tract	Abdominal pain, stomach pain, diarrhea and constipation
Other allergic reactions	Skin allergies and prurigo

H. Precautions, dosage and administration, and warnings for use of ingredients for improving intestinal health (Table 1 Category D).

[Precautions]

Ⅰ. Do not use in the following conditions:

(I)People who are allergic to the ingredient(s) of this product.

(II)People with low tolerance to milk or dairy food

(Must be indicated for preparations containing the ingredient listed in Table 1 Category D Group 1.)

Ⅱ. Under the following conditions, consult your doctor before use:

(I)Children under the age of 3 years.

III. **Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:**

(I)Pregnant women, women who might be pregnant or breastfeeding women.

IV. **Others:**

(I) Store properly to prevent children from accidentally taking this drug.

(II)Avoid direct sunlight.

(III)Do not exceed the stated dose.

(IV)Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose.

(Must be indicated for solutions.)

(V)The tablets must be chewed or melted in the mouth before swallowing.

(Must be indicated for the chewable tablet.)

(VI)When you have a fever, do not use for more than 48 hours.

(Must be indicated for preparations containing ingredients listed in Table 1 Category D Group 1.)

[Dosage and Administration]

Age	Dose
Adults and 12 years of age and over.	Three to four times a day or when needed.
Children 6 to less than 12 years of age.	1/2 of adult dosage.
Children 3 to less than 6 years of age.	1/4 of adult dosage.
Children under the age of 3 years.	Consult your doctor.

[Warnings]

I. After taking the preparation, if any of the following side effects occurred, please stop using it immediately, and bring the insert to consult your doctor, pharmacist or assistant pharmacist.

(I) The following information must be indicated for preparations containing ingredients listed in Table 1 Category D Group 1:

Body part	Side effects
Gastrointestinal tract	Flatulence occurs sometimes

Ⅱ. After taking the preparation, if any of the following symptoms occurred, please stop using it immediately and seek medical advice:

(I) Any discomfort occurs.

(II)If symptoms are not improved after taking this medicine for several days.

I. Precautions, dosage and administration, and warnings for use of ingredients for antidiarrheal ingredients (Table 1 Category E).

[Precautions]

I. Do not use in the following conditions:

(I)People who are allergic to the ingredient(s) of this product.

(II)People with bloody or black stool .

(Must be indicated for preparations containing kaolin).

II. Under the following conditions, consult your doctor before use:

(I) Children under the age of 6 years.

(II)Children under the age of 12 years.

(Must be indicated for preparations containing kaolin).

(III)People with fever or systemic symptoms, taking antibiotics recently, or with ulcerative colitis or similar symptoms.

(IV)People with viscous liquid in the stool.

(Must be indicated for preparations containing kaolin.)

(V)People with symptoms of acute diarrhea, such as vomiting, abdominal pain, or abdominal distension.

(Must be indicated for preparations containing astringent ingredients).

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I)Pregnant women, women who might be pregnant or breastfeeding women.

(II)People with low tolerance to milk or dairy food.

(Must be indicated for the excipients of the preparation containing lactose, and the amount of lactose of the daily maximum recommended dosage is greater than 5g.)

(III)People who are taking other drugs.

(Must be indicated for preparations containing kaolin).

IV. Others:

(I)Store properly to prevent children from accidentally taking this drug.

(II)Avoid direct sunlight.

(III)Do not exceed the stated dose.

(IV)The most important treatment for diarrhea is supplementing water and electrolytes. Antidiarrheal medicines must only be used as an adjuvant treatment.

(V)You might recover from mild diarrhea without taking medicine.

(VI)This medicine should be taken at least 3 hours apart from other drugs.

(Must be indicated for preparations containing kaolin).

(VII)Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose.

(Must be indicated for solutions.)

(VIII)The tablets must be chewed or melted in the mouth before swallowing.

(Must be indicated for the chewable tablet.)

(IX)Use of antidiarrheal drug should be at least four hours apart.

(X) In the event of acute diarrhea, must not be use for more than 48 hours.

[Dosage and Administration]

I. General antidiarrheal preparations

Age	Dose
Adults and 12 years of age and over.	Three to four times a day or when needed.
Children 6 to less than 12 years of age.	1/2 of adult dosage.
Children under the age of 6 years.	Consult your doctor.

II. Preparations containing kaolin from in Table 1 Category E Group 3:

Age	Dose
Adults and 12 years of age and over.	Three to four times a day or when needed.
Children under the age of 12 years.	Consult your doctor.

[Warnings]

I.After taking the preparation, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

(I)The following information must be indicated for preparations containing polycarbophil:

Body part	Side effects
Gastrointestinal tract	Constipation and occasional abdominal bloating[1]

II. After taking the preparation, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I)Any discomfort occurs.

(II)If symptoms are not improved after taking this medicine for several days.

(III)Conditions worsen or diarrhea continues for more than two days. (Must be indicated for preparations containing kaolin).

J. Precautions, dosage and administration, and warnings for use of ingredients for anti-flatulence (Table 1 Category F).

[Precautions]

I. Do not use in the following conditions:

(I)People who are allergic to the ingredient(s) of this product.

II. Under the following conditions, consult your doctor before use:

(I)Children under the age of 3 years.

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I)Pregnant women, women who might be pregnant, or breastfeeding women.

IV. Others:

(I) Store properly to prevent children from accidentally taking this drug.

(II)Avoid direct sunlight.

(III)Do not exceed the stated dose.

(IV)Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose.
(Must be indicated for solutions.)

(V)The tablets must be chewed or melted in the mouth before swallowing.
(Must be indicated for the preparations of chewable tablet dosage form.)

[Dosage and Administration]

Age	Dose
Adults and children 3 years or older.	Three to four times a day or when needed.
Children under the age of 3 years.	Consult your doctor.

[Warnings]

I. After taking the preparation, if any of the following symptoms occur, please stop using it immediately, and seek medical advice:

(I) Any discomfort occurs.

(II) If symptoms are not improved after taking this medicine for several days.

K. Precautions, dosage and administration, and warnings for the use of ingredients with local anesthesia (Table 1 Category G)

[Precautions]

I. Do not use in the following conditions:

(I)People who are allergic to the ingredient(s) of this product.

II. Under the following conditions, consult your doctor before use:

(I) Children under the age of 12 years.

(II)Pregnant women, women who might be pregnant, or breastfeeding women.

III. Others

(I) Store properly to prevent children from accidentally taking this drug.

(II)Avoid direct sunlight.

(III)Do not exceed the stated dose.

(IV)If there is excessive use, some patients might feel dizzy, faint or drowsy.

(V)Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose.

(Must be indicated for solutions.)

[Dosage and Administration]

Age	Dose
Adults and 12 years of age and over.	Three to four times a day or when needed.
Children under the age of 12 years.	Consult your doctor.

[Warnings]

I. After taking the preparation, if any of the following symptoms occured, please stop using it immediately, and seek medical advice:

Body part	Side effects
Other allergic reactions	Occasional allergies (skin rash, pruritus, glossitis and angioedema)

(I) Any discomfort occurs.

(II)If symptoms are not improved after taking this medicine for several days.

Table 2 Combination rules

Active ingredients \ Preparation name				Antiacid	Stomach health preparation	Digestant preparation	Intestine health preparation	General gastrointestinal preparation	Antidiarrheal preparation	Notes
Category A	Acidity neutralization	Group 1	Inorganic acidity neutralization (20 ingredients)	◎	○	○	○	At least two categories from Categories A, B, C and D are ◎; and the others are ○.	○	
		Group 2	Amino acid (2 ingredients)		○	○	○		○	
Category B	Stomach health	Group 1	Crude drug ingredient (43 ingredients)	○	◎	○	○		○	
		Group 2	l-Menthol	○		○	○		○	
		Group 3	Carnitine chloride	○		○	○		○	Should not be used in combination with ingredients from Category H.
		Group 4	Dry yeast	○		○	○		○	
Category C	Digestion	Group 1	(a) Pancreatic Enzymes (b) Other digestive enzymes	○	○	◎	○		○	Beta-galactosidase and pancrelipase are single-ingredient preparations only. Pancreatin should not be used in combination with pepsin.
		Group 2	Gallbladder health (5 ingredients)	○	○		○		○	
Category D	Intestinal health	Group 1	Intestinal viable bacteria (12 ingredients)	○	○	○	◎		○	*Bacillus coagulans*, *Bacillus mesentericus*, *Lactobacillus lactis* and *Lactobacillus rhamnosus* are single-ingredient preparations only.
		Group 2	Crude drug ingredient (2 ingredients)	×	○	○	○	○	○	Should not be used as essential composing ingredients
Category E	Antidiarrheals	Group 1	Sterilization (4 ingredients)	×	×	×	×	×	◎	Berberine chloride and berberine tannate should not be used in combination with Phellodendri cortex or Coptidis rhizoma.

		Group 2	Astringent (1 ingredient)	×	×	×	×	×		
		Group 3	Sorption (5 ingredients)	○	○	○	○	○		
		Group 4	Cover (1 ingredient)	○	○	○	○	○		
		Group 5	Attapulgite Calcium polycarbophil	×	×	×	×	×		Single-ingredient preparations only.
		Group 6	preparationCrude drug ingredient (6 ingredients)	×	△	△	△	△		△ means that it can be used in combination with the ingredients marked with △ in Table 1.
Category F	Anti-flatulence		Simethicone Dimethicone	○	○	○	○	○	×	Can be used in combination with at most one ingredient; or can be a single-ingredient preparation.
Category G	Local anesthesia		Oxethazaine	×	×	×	×	×	×	Can be used as a single-ingredient preparation, or be used in combination with ingredients from Category A only as a compound preparation.
Category H	Other		Scopolia extract Belladonna extract	○	○	○	○	○	○	Can be used in combination with at most one ingredient, but should not be used in combination with ingredients from Category B Group 3.

◎: Essential composing ingredient ○: Optional composing ingredients

△: Partial optional composing ingredient ×: Non-composing ingredient.

Table 3 Combination coefficient

Category	Group	Active ingredients	Combined with one ingredient from the same Category/Group		Combined with at least two ingredients from the same Category/Group (n: number of combination ingredients from the same Category/Group)			Notes
			Essential composing ingredients (◎)	Optional composing ingredients (○/△)	Essential composing ingredients (◎)	Optional composing ingredients (○/△)	Lower limit for the Daily dose of each ingredient	
A. Acidity neutralization	1 2	Inorganic acidity neutralization Amino acid	150mL≦ ≦1	75mL≦ ≦1	150mL≦ ≦2	75mL≦ ≦2	Not specified.	When an ingredient is not combination as an active ingredient, the combination coefficient for that ingredient must be less than 1/5; if it is not less than 1/5, the consumption of 0.1N HCL of the daily dose for the preparation must be less than 75 mL.
B. Stomach health	1 2	Crude drug ingredient l-Menthol	1/2≦ ≦1	1/10≦ ≦1	1/2≦ ≦2 (n=2) 1/2≦ ≦3 (n≧3)	1/10≦ ≦2 (n=2) 1/10≦ ≦3 (n≧3)	Not specified.	When an ingredient is not combination as an active ingredient, the combination coefficient of the ingredient must be less than 1/10;
	3	Carnitine chloride	1/2≦ ≦1	1/5≦ ≦1				
	4	Dry yeast	1/2≦ ≦1	1/5≦ ≦1				
C. Digestion	1	(a) Pancreatic Enzymes	Based on Table 1.	Based on Table 1	Based on Table 1	Based on Table 1.	Based on Table 1	
		(b) Other digestive enzymes	Based on Table 1.	Based on Table 1	Based on Table 1	Based on Table 1.	Based on Table 1.	
	2	Gallbladder health	1/2≦ ≦1	1/5≦ ≦1	1/2≦ ≦1	n/5≦ ≦1	1/5	
D. Intestinal health	1	Intestinal viable bacteria	$\leqq 10^6$	$\leqq 10^6$	$\leqq 10^6$	$\leqq 10^6$	Not specified	

	2	Crude drug ingredient		1/10≦ ≦1		n/10≦ ≦2	1/10	
E. Antidiarrheals	1	Sterilization	1/2≦ ≦1	1/5≦ ≦1	1/2≦ ≦1	n/5≦ ≦1	1/5	
	2	Astringent	1/2≦ ≦1	1/5≦ ≦1	1/2≦ ≦1	n/5≦ ≦1	1/5	
	3	Sorption	1/2≦ ≦1	1/5≦ ≦1	1/2≦ ≦1	n/5≦ ≦1	1/5	Whenever calculating the lower limit of combination coefficient and the daily dose for Medicinal carbon, the Maximum daily dose used is 2.0g.
	4	Cover	1/2≦ ≦1	1/5≦ ≦1	1/2≦ ≦1	n/5≦ ≦1	1/5	
	5	Attapulgite Calcium polycarbophil	≦1					
	6	Crude drug ingredient	1/2≦ ≦1	1/10≦ ≦1	1/2≦ ≦2	n/10≦ ≦2	1/10	
F. Anti-flatulence		Simethicone Dimethicone	1/5≦ ≦1	1/5≦ ≦1				
G. Local anesthesia		Oxethazaine	1/5≦ ≦1					
H. Other		Scopolia extract Belladonna extract		1/5≦ ≦1				

Antipyretic and analgesic drug products

A. Scope

This guideline applies to preparations for antipyretic and analgesic purposes that are administered orally or are rectal suppositories.

B. Active ingredients

I.Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II)Table 1 stipulates the maximum single dose and the maximum daily dose for each active ingredient in categories A and B. For ingredients from Category A, either Group I or Group II may be chosen.

(III)Table 1 stipulates the upper and lower limits of the daily dose for each ingredient from Category C, and the maximum daily dose for each active ingredient from Category D.

Table 1. Active ingredient and dose

Category	Group	Active ingredients	Maximum single dose (Maximum unit content) *1 (mg)		Maximum daily dose (mg)	
			Group I	Group II	Group I	Group II
A	1	Acetaminophen	325	1000 (500) *1	1600	4000
	2	Aspirin	500	1000 (500) *1	1600	4000
	3	Ethenzamide	500	—	1500	—
		Salicylamide	325	—	1600	—
B		Caffeine	120		300	
		Caffeine anhydrous	120		300	

Table 1. Active ingredient and dose (continued)

Category	Group	Active ingredients		Daily dose (mg)
C	1	Vitamin B_1		1.8-30
		Active ingredients	● Bisbentiamine ● Bisibutiamine ● Cetotiamine hydrochloride ● Cycotiamine ● Dibenzoyl thiamine ● Dibenzoyl thiamine hydrochloride ● Fursultiamine hydrochloride ● Octotiamine ● Prosultiamine ● Thiamine hydrochloride (Vitamin B_1) ● Thiamine mononitrate ● Thiamine dicetylsulfate ● Thiamine disulfide	
	2	Vitamin B_2		2.25-10
		Active ingredients	● Riboflavin (Vitamin B_2) ● Riboflavin butyrate ● Riboflavin sodium phosphate	
	3	Vitamin C		82.5-500
		Active ingredients	● Ascorbic acid (Vitamin C) ● L-Ascorbyl palmitate ● L-Ascorbyl stearate ● Calcium ascorbate ● Sodium ascorbate	

Category	Group	Active ingredients	Maximum daily dose (g) *2	
			Extracts (amount converted from crude drug ingredient)	Powders
D		Glycyrrhizae radix	5	1.5
		Cinnamomi cortex	5	1
		Zingiberis rhizoma	3	1
		Paeoniae radix	5	2

*1. Maximum unit dose: To limit the maximum dose of the active ingredients in each unit of preparation in tablet, capsule, suppository, powder, etc. form (e.g., per tablet, per capsule, per sachet, etc.).

*2. Extract and powder of the same ingredient must not be used together. The maximum daily dose for an extract is expressed as the amount of the original crude drug ingredient used to make the extract.

II. Combination rules (see Table 2):

(I) Essential composing ingredients:

1. The essential composing ingredients of Group Ⅰ preparations: The active ingredients in Category A of Table 1. The formula must contain at least one essential composing ingredient, and at most three ingredients can be combined.
2. The essential composing ingredients of Group II preparations: The active ingredients in Category A Groups 1 and 2 of Table 1. The formula must contain at least one essential composing ingredient, and at most two ingredients can be combined.

(II) Optional composing ingredients:

1. The active ingredients in Categories B, C and D of Table 1, which can be used in combination with essential composing ingredients from Category A. However, a formulation basis adopted in one of the ten advanced countries should be submitted when an active ingredient in category D is used for Group II preparation.
2. Ingredients in Category B can be combined at most one active ingredient.

(III) Qualitative tests shall be carried out for preparations containing crude drug ingredients (Table 1 Category D); and quantitative tests shall be carried out for crude drug ingredients with indicator ingredients as recorded in the pharmacopoeias.

III. Combination dose of active ingredients (see Table 2):

(I)Ingredients from Table 1 Category A:

1. The maximum single dose and the maximum daily dose for each active ingredient must meet the requirements in the corresponding group for the preparation in Table 1.
2. The one-time dose and daily maximum dose of each active ingredient must not exceed the maximum single dose and maximum daily dose stipulated in Table 1. When the Group II preparations contain acetaminophen or aspirin, the unit maximum dose for each preparation can not exceed the maximum unit dose stipulated in Table 1.
3. When an active ingredient in one Category is composed, the combination coefficient for that category should be between 1 and 1/2.
4. Group I preparation: When two or three active ingredients from the same Category are used in combination, the combination coefficient for that category must be between 38/30 and 1/2; and the lower limit of the combination coefficient for the daily dose of each composing ingredient in that category can not be less than 1/5.
5. Group II preparation: When two active ingredients from the same Category are used in combination, the combination coefficient for that category must be between 1 and 1/2, and the lower limit of the combination coefficient for the daily dose of each composing ingredient in that category can not be less than 1/5.
6. Combination coefficients $= \Sigma (X_i/mX_i)$

   $= (X_1 / mX_1)+(X_2 / mX_2)+\ldots\ldots+(X_n / mX_n)$

   X_i: Daily dose of the composing ingredient i from each category

   mX_i: Maximum daily dose for the composing ingredient i from each category. (Group I preparations and Group II preparations must use the stipulated maximum daily dose for the corresponding group.)

n: Number of composing ingredients in each category.

(II)When the formula contains an ingredient in Category B of Table 1:

1. The one-time dose and daily maximum dose of each active ingredient must not exceed the maximum single dose and maximum daily dose stipulated in Table 1.
2. When the formula contains an active ingredient in Category B, the combination coefficient of that category must be between 1 and 1/5.
3. Combination coefficient = X/mX

   X: The daily dose of composing ingredient x in Category B.

   mX: The maximum maximum daily dose of composing ingredient x in Category B.

(III)When the formula contains an ingredient in Category C of Table 1:

1. The daily dose of the ingredients in Category C shall follow the upper and lower limits stipulated in Table 1.
2. When two or more ingredients from Category C Groups 1, 2 and 3 are combined, the combination coefficient cannot be greater than 1. In other words, the sum of the ratio of daily dose to the maximum daily dose of each ingredient shall not exceed 1.
3. Combination coefficients＝Σ (Xi/mXi)

   ＝ (X1 / mX1)+(X2 / mX2)+……+(Xn / mXn)

   Xi: Daily dose of the composing ingredient i from Category C.

   mX_i: Maximum daily dose of the composing ingredient i from Category C.

   n: Number of composing ingredients in Category C.

(IV)When the formula contains ingredients from Table 1 Category D:

1. When an active ingredient in one Category is composed, the combination coefficient for that category should be between 1 and 1/10.
2. When two or more ingredients from the same Category are combined, the combination coefficient for that composing ingredient can not be greater than 1, and the lower limit for the combination coefficient for the daily maximum dose of each composing ingredient in that category can not be less than 1/10.
3. Combination coefficients＝Σ (Xi/mXi)

   ＝ (X1 / mX1)+(X2 / mX2)+……+(Xn / mXn)

   Xi: Daily dose of the composing ingredient i from Category D.

   mXi: Maximum daily dose of the composing ingredient i from Category D.

   n: Number of composing ingredients in Category D.

C. Dosage form

I. Limited to tablets, film coated tablets, sugar coated tablets, capsules, soft capsules, oral solutions, suspension solutions, syrups, powders, powders for solution, powders for syrup, granules for internal use, granules for syrup, and fine granules.

II. For oral solutions (including syrups), the one-time dose for an adult must be 5 ml or more. The maximum package of selling unit may not exceed three days.

III. Products containing salicylates can be enteric coated dosage form.

IV. Single-ingredient preparations containing ingredient from Category A Groups 1, 2 or salicylamide of Group 3 may be in the form of suppositories.

D. Use (indication)

Reducing fever, relief of pain (relief of headache, toothache, sore throat, joint pain, neuralgia, muscular ache, or menstrual pain).

E. Precautions

I. **Do not use in the following conditions:**

(I) People who are allergic to the ingredient(s) of this product.

(II)People with favism (G6PD-deficiency).

(Must be indicated for preparations containing salicylic acid.)

(III) Women who are 28 weeks or more pregnant.

(Must be indicated for preparations containing salicylic acid.)

(IV) The elimination of chickenpox or influenza symptoms under 18 years of age. May cause rare but serious Reye's Syndrome.

(Must be indicated for preparations containing salicylic acid.)

(V)People with diarrhea.

(Must be indicated for suppositories.)

II. **Under the following conditions, consult your doctor before use:**

(I) Children under the age of 3 years.

(With exception of preparations containing salicylic acid.)

(II) Adults who take this medicine for more than 7 days and children under the age of 12 years for more than 3 days, without alleviation of symptoms.

(III) People with peptic ulcers or who are using anticoagulants.

(Must be indicated for preparations containing salicylates.)

(IV) People with high blood pressure, cardiac dysfunction or renal dysfunction. [Must be indicated for preparations containing more than 1g Glycyrrhizae radix from Table 1 Category D (or more than 1g of the crude drug ingredient for extract).]

(V) Children under the age of 12 years.

(Must be indicated for preparations containing caffeine.)

(VI) People with liver diseases.

(Must be indicated for preparations containing acetaminophen.)

III. **Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:**

(I) Pregnant women, women who might be pregnant, and breastfeeding women.

(II) Adults aged 65 years and over or who have edema symptoms.

[Must be indicated for preparations containing more than 1g Glycyrrhizae radix from Table 1 Category D (or more than 1g of the crude drug ingredient for extract).]

(III) People who have had peptic ulcers.

(Must be indicated for preparations containing salicylates.)

(IV) People who are taking painkillers, antipyretics or common cold medicines containing acetaminophen.

(Must be indicated for preparations containing acetaminophen.)

IV. Other:

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III) Do not exceed the stated dose.

(IV) Excessive acetaminophen use may occur due to a desire for quicker or stronger analgesic effects, or due to repeatedly take medicines containing acetaminophen without knowing or noticing. However, taking more than 4,000 mg acetaminophen per day will cause liver damage.

(Must be indicated for preparations containing acetaminophen.)

(V) Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose.

(Must be indicated for suspension solutions.)

(VI) Anal administration only. Do not use if the suppository has deformed due to it being excessively soft.

(Must be indicated for suppositories.)

(VII) Alcohol warnings: Do not take this medicine with alcoholic beverages, because acetaminophen (paracetamol) carries a risk of acute liver failure.

(Must be indicated for preparations containing acetaminophen.)

(VIII) Alcohol warnings: Do not take this medicine with alcoholic beverages; there are risks of acute liver failure and stomach bleeding.

(Must be indicated for preparations containing acetaminophen when they are in combination with salicylates.)

(IX) Alcohol warnings: Do not take this medicine with alcoholic beverages, because this may result in stomach bleeding.

(Must be indicated for preparations containing salicylates.)

(X) Avoid taking medicines or drinks containing caffeine. Too much caffeine can cause nervousness, excitement and insomnia, and often results in tachycardia. To avoid dependence and liver and kidney damage, it must not be used for a long time.

(Must be indicated for preparations containing caffeine.)

F. Dosage and Administration

I. Preparations containing acetaminophen:

Adults and 12 years of age and over.	1. Group I preparation: Use when there is fever or when needed. If symptoms continue, take it again every 4 to 6 hours. Do not take more than ◯ times within 24 hours. 2. Group II preparation: Use when there is fever or when needed. If symptoms continue, take it again every 4 to 6 hours, ◯~◯ tablets (or pills, sachets, etc.) each time. Take the minimum recommended dose the first time, and increase the dose as required by symptoms. Do not take more than ◯ times within 24 hours.
Children 6 to less than 12 years of age.	1/2 of adult dosage.
Children 3 to less than 6 years of age.	1/4 of adult dosage.
Children under the age of 3 years.	Consult your doctor.

II. Preparations containing salicylates

Adults and children 18 years or older.	1. Group I preparation: (1) Use when there is fever or when needed. If symptoms continue, take it again every 4 to 6

	hours. Do not take more than ◯ times within 24 hours. (2) Oral preparations: Better taken within 30 minutes after meal. 2. Group II preparation: (1) Use when there is fever or when needed. If symptoms continue, take it again every 4 to 6 hours, ◯~◯ tablets (or pills, sachets, etc.) each time. Take the minimum recommended dose the first time, and increase the dose as required by symptoms. Do not take more than ◯ times within 24 hours. (2) Oral preparations: Better taken within 30 minutes after meal.
Children under 18 years of age	Do not use.

III. Drug must be swallowed whole and must not be halved or chewed.
(Must be indicated for enteric coated preparations.)

IV. The drug cannot be halved.
(Must be indicated for suppositories.)

G. Warnings

I. After taking the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

Body part	Side effects
Skin	Rash and redness.
Digestive organs	Nausea, vomiting, loss of appetite,

	gastrointestinal discomfort, gastrointestinal bleeding
Nervous system	Dizziness and tinnitus
Other	Tendency toward bleeding; asthma.

(Must be indicated for preparations containing salicylates (Table 1 Category A Group 2 and Group 3).)

Body part	Side effects
Skin	Rash, redness.
Digestive organs	Nausea, vomiting, loss of appetite.
Nervous system	Dizziness, tinnitus.

(Must be indicated, except with preparations containing salicylate.)

II. After taking the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Any discomfort occurs.

(II) After taking this medicine for three days, fever and pain symptoms do not improve.

(III) A decrease in urine output, swelling of the face or hands and feet, heavy eyelids, stiff hands, elevated blood pressure or headache. [Must be indicated for preparations containing more than 1g Glycyrrhizae radix in Table 1 Category D (or more than 1g of the crude drug ingredient for extract).]

(IV) Excessive use [more than 4,000 mg per day], or appearance of the following symptoms after using this medicine: Gastrointestinal discomfort, anorexia, nausea, vomiting, paleness and sweating. (Must be indicated for preparations containing acetaminophen.)

(V) Allergic reactions, such as Swelling of face, mouth or throat; difficulty breathing; urticaria; rash or other skin irritation; itching

and vomiting. (Must be indicated for preparations containing acetaminophen.)

Table 2 Combination rules and combination coefficients

Active ingredient			Group I preparation				Group II preparation				Notes
			Combination rules	Combined with one ingredient from the same Category	Combined with at least two ingredients from the same Category		Combination rules	Combined with one ingredient from the same Category	Combined with at least two ingredients from the same Category		
				Combination coefficient	Combination coefficient	Lower limit for the maximum daily dose of each ingredient		Combination coefficient	Combination coefficient	Lower limit for the maximum daily dose of each ingredient	
Category A	Group 1		◎	1/2≦ ≦1	1/2≦≦ 38/30	1/5	◎	1/2≦ ≦1	1/2≦ ≦1	1/5	● Must contain at least one. ● Group I preparations can be used in combination with at most three ingredients. ● Group II preparations can be used in combination with at most two ingredients.
	Group 2		◎				◎				
	Group 3		◎				×				
Category B	Caffeine		○	1/5≦ ≦1			○	1/5≦ ≦1			Can be combined with at most one ingredient.
Category C	Group 1	Vitamin B_1	○	Based on Table 1	≦1	Based on Table 1	○	Based on Table 1	≦1	Based on Table 1	Based on Table 1: Based on the upper and lower limits of maximum daily dose stipulated in Table 1.
	Group 2	Vitamin B_2	○	Based on Table 1	≦1	Based on Table 1	○	Based on Table 1	≦1	Based on Table 1	
	Group 3	Vitamin C	○	Based on Table 1	≦1	Based on Table 1	○	Based on Table 1	≦1	Based on Table 1	

Category D	Crude drug ingredient	◯	1/10≦ ≦1	≦1	1/10	◯	1/10≦ ≦1	≦1	1/10	If ingredients from Category F are used in combination with Group II preparation, the prescription used by one of the ten advanced countries must be submitted as evidence.

◎: Essential composing ingredient ○: Optional composing ingredients

General common cold medicines

A. Scope

This guideline applies to oral preparations that contain any two or more ingredients for antipyretic or analgesic effect, antihistamine, antitussive or expectorant effect, decongestion or bronchiectasis, as well as to day formula and night formula composite packages.

B. Active ingredients

I. Active ingredient and dose:

(I)The active ingredients specified in Table 1 are applicable to this guideline.

(II)Table 1 stipulates the maximum single dose and the maximum daily dose for each active ingredient in Categories A, B, C, D and E. One of three groups may be chosen.

(III)Table 1 stipulates the maximum daily dose for each active ingredient in Category F and Category H, and the upper and lower limits of the daily dose for each ingredient in Category G.

Table 1. Active ingredient and dose

Category	Group	Active ingredients	Maximum single dose (mg)[*1]			Maximum daily dose (mg)[*1]		
			Group I	Group II	Group III	Group I	Group II	Group III
A		Acetaminophen (Paracetamol)	325	500	—	1,600 (900) [*2]	2,000	—
		Aspirin	500	500	—	1,600	2,000	—
		Ethenzamide	500	—	—	1,500	—	—
		Salicylamide	325	—	—	1,600	—	—
B		Brompheniramine maleate	—	4	—	—	24	—
		Carbinoxamine maleate	2.5	—	4	8	—	12

Table 1. Types of active ingredients (continued)

Category	Group	Active ingredient	Maximum single dose (mg)[*1]			Maximum daily dose (mg)[*1]		
			Group I	Group II	Group III	Group I	Group II	Group III
B		Chlorcyclizine hydrochloride	—	25	—	—	75	—
		Chlorpheniramine maleate (dl-Chlorpheniramine maleate)	2.5	4	4	8	24	12
		Dexchlorpheniramine maleate (d-Chlorpheniramine maleate)	1.17	2	2	4	12	6
		Diphenhydramine hydrochloride	25	50	30	75	300	90
		Diphenhydramine salicylate	25	—	40	75	—	120
		Diphenhydramine tannate	25	—	50	75	—	150
		Diphenylpyraline hydrochloride	1.33	—	2	4	—	6
		Pheniramine maleate	—	25	—	—	150	—
		Pyrilamine maleate	—	50	—	—	200	—
		Triprolidine hydrochloride	1.33	2.5	2	5	10	6
		Doxylamine hydrochloride	—	12.5	—	—	75	—
C	1	Carbetapentane citrate (Pentoxyverine citrate)	16	—	20	60	—	60
		Cloperastine hydrochloride	16	—	20	60	—	60
		Dextromethorphan hydrobromide	16	20	20	60	120	60
		Noscapine	16	—	20	60	—	60
		Noscapine hydrochloride	16	—	20	60	—	60
		Tipepidine citrate	20	—	20	60	—	60
		Tipepidine hibenzate	25	—	25	80	—	75
	2	Guaiphenesin (Guaiacol glyceryl ether)	200	400	100	800	2,400	300
		Potassium guaiacolsulfonate	83.33	—	90	250	—	270
		Potassium cresolsulfonate	—	—	90	—	—	270
D	1	Phenylephrine hydrochloride	5	10	—	20	60	—
		Pseudoephedrine hydrochloride	30	60	—	120	240	—
		Pseudoephedrine sulfate	—	60	—	—	240	—
	2	Ephedrine hydrochloride	—	25	—	—	150	—
		dl-Methylephedrine hydrochloride	20	—	25	60	—	75
		Ephedrine sulfate	—	25	—	—	150	—
E		Caffeine	50	—	100	150	—	300
		Caffeine anhydrous	50	—	100	150	—	300

Table 1. Types of active ingredients (continued)

Category	Group	Active ingredient	Maximum daily dose (mg)		
			Group I	Group II	Group III
F		Aluminum hydroxide gel is equivalent to aluminum hydroxide dried gel.	1,000	—	1,000
		Aluminum hydroxide dried gel	1,000	—	1,000
		Aluminum hydroxide-magnesium carbonate co-dried gel	1,500	—	1,500
		Aluminum magnesium metasilicate	1,500	—	1,500
		Aluminum magnesium silicate	1,000	—	1,000
		Synthetic aluminium silicate	3,000		3,000
		Aminoacetic acid (Glycine)	900	—	900
		Dihydroxyaluminum aminoacetate (Aluminum glycinate)	1,500	—	1,500
		Dihydroxyaluminum sodium carbonate	1,000	—	1,000
		Hydrotalcite	2,000	—	2,000
		Magnesium carbonate	1,000	—	1,000
		Magnesium oxide	500	—	500
		Magnesium silicate (Magnesium trisilicate)	3,000	—	3,000
Category	Group	Type	daily dose (mg)		
			Group I	Group II	Group III
G	1	Vitamin B_1	1.8-30	1.8-30	—
		Combination ingredients: Bisbentiamine, Bisibutiamine, Cetotiamine hydrochloride, Cycotiamine, Dibenzoyl thiamine, Dibenzoyl thiamine hydrochloride, Fursultiamine hydrochloride, Octotiamine, Prosultiamine, Thiamine hydrochloride, Thiamine mononitrate, Thiamine dicetylsulfate, Thiamine disulfide			

Table 1. Types of active ingredients (continued)

Category	Group	Type		daily dose (mg)		
				Group I	Group II	Group III
G	2	Vitamin B_2		2.25-10	2.25-10	—
		Combination ingredients	Riboflavin (Vitamin B_2) Riboflavin butyrate Riboflavin sodium phosphate			
	3	Vitamin C		82.5-500	82.5-500	—
		Combination ingredients	Ascorbic acid (Vitamin C) L-Ascorbyl palmitate L-Ascorbyl stearate Calcium ascorbate Sodium ascorbate			
	4	Hesperidine		18-90	18-90	—

Category	Group	Active ingredient	Maximum daily dose (g)[*3]			
			Extracts (amount converted from crude drug ingredient)		Powder	
			Group I	Group III	Group I	Group III
H	1	Ephedrae herba	4	4	—	—
	2	Glycyrrhizae radix	5	5	1.5	1.5
		Platycodi radix	4	4	2	2
		Senegae radix	4	4	1.5	1.5
	3	Cinnamomi cortex	5	5	1	1
		Ginseng radix	6	6	3	3
		Zingiberis rhizoma	3	3	1	1
	4	Paeoniae radix	5	—	2	—
		Puerariae radix	8	—	—	—
		Zizyphi fructus	4	—	—	—

*1. If the maximum single dose and maximum daily dose for each active ingredient in Categories A, B, C and D are not stipulated for Groups I, II or III, the preparations in those groups may not be used in combination with that ingredient.

*2. When Group I preparations are used in combination with acetaminophen and other active ingredients from Category A, the maximum daily dose used for calculating the combination coefficient for that category and the lower limit of the daily dose of acetaminophen is 900mg.

*3. Extract and powder of the same ingredient must not be used together. If there is no maximum daily dose for the powder, the ingredient must not be used as a powder in combination. The maximum daily dose for an extract is expressed as the amount of the crude drug ingredient used to make the extract.

II. Combination rules (see Table 2):

(I) Group I:

1. Main essential composing ingredients: The active ingredients in category A of Table 1. The formula for common cold drug products in Group I must contain at least one main essential composing ingredient; at most two main essential composing ingredients can be combined.
2. Main optional composing ingredients: The active ingredients in Categories B, C and D of Table 1. The formula for common cold drug products in Group I must contain at least one main optional composing ingredient.
3. Optional composing ingredients: The active ingredients in Categories E, F, G and H of Table 1, which can be used in combination with the main essential composing ingredients and the main optional composing ingredients.
4. The ingredients in Categories B, D and E of Table 1 can be used in combination with at most one active ingredient in each category.
5. The active ingredients in Category C Group 1 and Group 2 of Table 1 can be used in combination with at most one active ingredient in each Group.
6. The ingredients in Category D of Table 1 cannot be used in combination with ephedrae herba in Category H Group 1.

(II) Group II:

1. Main essential composing ingredients: The active ingredients in Categories A, B, C and D of Table 1. The formula for common cold

drug products in Group II must contain the main essential composing ingredients from at least two different categories.

2. Optional composing ingredients: The active ingredients in Categories E, F and G of Table 1, which can be used in combination with the main essential composing ingredients as compound preparations. However, when combined with ingredients in Category E and Category F, the formulation basis adopted in one of the ten advanced countries must be submitted as evidence.
3. The active ingredients in Category A of Table 1 can be used in combination with at most two active ingredients.
4. The ingredients in Categories B, D and E of Table 1 can be used in combination with at most one active ingredient in each category.
5. The active ingredients in Category C Group 1 and Group 2 of Table 1 can be used in combination with at most one active ingredient in each Group.

(III) Group III:

1. Main essential composing ingredients: The active ingredients in Categories B, C and D of Table 1. The formula for common cold drug products in Group III must contain the main essential composing ingredients from at least two different categories.
2. Optional composing ingredients: The active ingredients in Categories E, F and H of Table 1, which can be used in combination with the main essential composing ingredients.
3. The ingredients in Categories B, D and E of Table 1 can be used in combination with at most one active ingredient in each category.
4. The active ingredients in Category C Group 1 and Group 2 of Table 1 can be used in combination with at most one active ingredient in each Group.

5. The ingredients in Category D of Table 1 cannot be used in combination with ephedrae herba in Category H Group 1.
6. The ingredients in Category E of Table 1can only be used in combination with preparations containing the ingredients in Category B (antihistamine) or Category C Group 1 (antitussive ingredients).

(IV) Qualitative tests shall be carried out for preparations in Group I and Group III containing crude drug ingredients (Table 1 Category H); and quantitative tests shall be carried out for crude drug ingredients with indicator ingredients as recorded in the pharmacopoeias.

(V) The combination rules for the day and night formula package shall comply with one of the following principles:

1. If the day formula does not contain the ingredients in Category B (antihistamine), the night formula shall contain them.
2. If both the day and night formulas contain the ingredients in Category B (antihistamine), the day formula shall contain the ingredients in Category E (caffeine).

III. Combination dose of active ingredients (see Table 2):

(I) In common cold drug products preparations, the maximum single dose and the maximum daily dose for each active ingredient must meet the requirements in the corresponding group for the preparation in Table 1.

(II)In Categories A, B, C, D and E of Table 1, the one-time dose for each active ingredient may not exceed the maximum single dose stipulated in Table 1.

(III)When the preparations contain oral solutions (including syrup) with antipyretic and analgesic ingredients, the maximum single dose and maximum daily dose for each active ingredient are 1/2 of the dose stipulated in Table 1. (For ingredients with a lower limit in Table 1,

the lower limit dose is also 1/2 of the lower limit stipulated in Table 1.) However, this excludes packages containing only one dose.

(IV) The combination coefficient for Category A should be between 1 and 1/2. When two active ingredients in Category A of Table 1 are used simultaneously in combination, the daily dose for each composing ingredient in the category can not be less than 1/5 of its maximum daily dose.

When combined with one ingredient:

Combination coefficient = X/mX

When combined with two ingredients:

Combination coefficient = (X/mX)+(Y/mY)

X (or Y): Daily dose of composing ingredient x (or y) from Category A.

mX (or mY): Maximum daily dose of composing ingredient x (or y) from Category A.

(V) When the formula contains ingredients from Category B, Category C Groups 1 or 2, or Category D, the combination coefficient for that category should be between 1 and 1/2.

Combination coefficient = X/mX

X: Daily dose of composing ingredient x from Category B (Category C Group 1 or 2, or Category D).

mX: Maximum daily dose for composing ingredient x from Category B (Category C Group 1 or Group 2, or Category D).

(VI) When the formula contains ingredients from Table 1 Category E or Category F:

1. When an active ingredient in one Category is composed, the combination coefficient for that category should be between 1 and 1/5.

2. When two or more active ingredients in Category F are used in combination, the combination coefficient for Category F should be between 1 and 1/2, and the daily dose for each composing ingredient in the category can not be less than 1/5 of the maximum daily dose.
3. Combination coefficients $= \sum_{i=1}^{n} (X_i/mX_i)$
   $= (X_1 / mX_1)+(X_2 / mX_2)+\ldots\ldots+(X_n / mX_n)$
   X_i: Daily dose of the composing ingredient i from Category E (or Category F).
   mX_i: Maximum daily dose of the composing ingredient i from Category E (or Category F).
   n: Number of composing ingredients from Category E (or Category F).
4. When used in combination with the Group II preparations, the maximum single dose and maximum daily dose from Category E and maximum daily dose from Category F should follow the dose stipulated for Group I in Table 1.

(VII) When the formula contains ingredients from Table 1 Category G:

1. When an active ingredient in one Group is composed, the dose of the ingredient shall follow the daily dose stipulated in Table 1.
2. When two or more ingredients from the same Group are combined, the combination coefficient cannot be greater than 1, and the daily dose for each composing ingredient in that Group can not be less than the lower limit of the daily dose for the ingredient.
3. Combination coefficients $= \sum_{i=1}^{n} (X_i/mX_i)$
   $= (X_1 / mX_1^{i=1})+(X_2 / mX_2)+\ldots\ldots+(X_n / mX_n)$
   X_i: Daily dose of composing ingredient i from Category G Group 1 (or Groups 2, 3, or 4)

mX_i: Maximum daily dose of composing ingredient i from Category G Group 1 (or Groups 2, 3, or 4)

n: Number of composing ingredients from Category G Group 1 (or Groups 2, 3, or 4)

(VIII) When the formula contains ingredients from Table 1 Category H:

1. When an active ingredient in one Group is composed, the combination coefficient for that Group should be between 1 and 1/10.
2. For ingredients from Category H Groups 2, 3 and 4, when two or more ingredients in the same Group are used in combination, the combination coefficient cannot be greater than 1, and the daily dose for each composing ingredient of that Group can not be less than 1/10 of its maximum daily dose.
3. The maximum single dose for each composing ingredient from Category H is 1/3 of the maximum daily dose.
4. Combination coefficients $= \sum_{i=1}^{n} (X_i/mX_i)$

   $= (X_1 / mX_1)+(X_2 / mX_2)+\ldots\ldots+(X_n / mX_n)$

   X_i: Daily dose of composing ingredient i from Category H Group 1 (or Groups 2, 3, or 4).

   mX_i: Maximum daily dose of composing ingredient i from Category H Group 1 (or Groups 2, 3, or 4)

   n: Number of composing ingredients from Category H Group 1 (or Groups 2, 3, or 4)

(IX)In the Group I formulas, if ingredients from Category D or Category H Group 1 are used in combination with ingredients from Category E, the sum of the ratio of the daily dose to the maximum daily dose for each ingredient from Category D (or Category H Group 1) and Category E can not be greater than 3/2.

(X)In the Group III formula, if ingredients from Category D or Category H Group 1 are combined with the ingredients in category E, the maximum single doses and maximum daily doses of ingredients from Category E should be 1/2 of those specified in Table 1.

C. Dosage form

Limited to tablets, film coated tablets, sugar coated tablets, capsules, soft capsules, oral solutions, syrups, powders, powders for solution, powders for syrup, granules for internal use, granules for syrup, and fine granules.

D. Use (indications)

To relieve the symptoms of cold (runny nose, stuffy nose, sneezing, sore throat, cough, phlegmy cough, chills, fever, headache, joint pain and muscle ache).

I. Descriptions of the symptoms in parentheses vary according to the ingredients (see Table 3). If the ingredients are not used, the symptoms cannot be indicated.

II. When the active ingredients in Table 1 Categories E, F, G or H are used in combination, the indications for those ingredients cannot be indicated.

Table 3 Indications

Category	Group	Combination ingredients	Symptoms of the indication
A		Antipyretic and analgesic ingredient	Sore throat, chills, fever, headache, joint pain and muscular ache
B		Antihistamine	Runny nose, stuffy nose and sneezing
C	1	Antitussive ingredient	Cough

	2	Expectorant	Phlegmy cough
D	1	Decongestant	Stuffy nose
	2	Bronchodilator	Cough and phlegmy cough

E. Precautions

I. Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product.

(II) Breastfeeding women.

(Must be indicated for preparations containing diphenhydramine hydrochloride, diphenhydramine salicylate or diphenhydramine tannate.)

(III) People with favism (G6PD-deficiency).

(Must be indicated for preparations containing salicylates.)

(IV) Women who are 28 weeks or more pregnant.

(Must be indicated for preparations containing salicylates.)

(V) The elimination of chickenpox or influenza symptoms under 18 years of age. May cause rare but serious Reye's Syndrome.

(Must be indicated for preparations containing salicylates.)

(VI) People taking monoamine oxidase inhibitors (MAOIs) or selective serotonin reuptake inhibitors (SSRIs).

(Must be indicated for preparations containing dextromethorphan.)

(VII) While taking MAOIs or within two weeks after discontinuation of MAOIs. If you do not know whether the drugs you are taking contain an MAOI, please ask your doctor or pharmacist.

(Must be indicated for preparations containing decongestants, such as phenylephrine hydrochloride, pseudoephedrine hydrochloride and pseudoephedrine sulfate.)

II. Under the following conditions, consult your doctor before use:

(I) Children under the age of 6 years.

(II) People with peptic ulcers or who are using anticoagulants.

(Must be indicated for preparations containing salicylates.)

(III) Children under the age of 12 years.

(Must be indicated for preparations containing chlorcyclizine hydrochloride, ephedrine hydrochloride or caffeine from Category E.)

(IV) People with liver, kidney disease or other serious diseases.

(V) People with persistent or chronic cough caused by smoking, asthma, or chronic obstructive pulmonary diseases (such as chronic bronchitis or emphysema).

(VI) You have a history of the following diseases: Heart disease, high blood pressure, diabetes, hyperthyroidism, or difficulty in urination due to prostatic hyperplasia.

(Must be indicated for preparations containing decongestants in Table 1 Category D Group 1, such as phenylephrine hydrochloride, pseudoephedrine hydrochloride and pseudoephedrine sulfate.)

(VII) You have a history of respiratory disease, such as chronic bronchitis, emphysema, chronic lung disease, shortness of breath, difficulty breathing, and people with glaucoma [, as well as people with difficulty in urination due to prostatic hyperplasia].

(Must be indicated for preparations containing antihistamine in Table 1 Category B.) If the words in brackets ([ ]) are indicated in the preceding Group, they need not be repeated.)

(VIII) People with heart disease or adults aged 65 years and over.

(Must be indicated for preparations containing bronchodilators from Category D Group 2 or crude drug ingredients from Category H Group 1.)

(IX) People with high blood pressure, cardiac dysfunction or renal dysfunction.

[Must be indicated for preparations containing more than 1g Glycyrrhizae radix in Category H Group 2 (or more than 1g of the crude drug ingredient for extract).]

III. **Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:**

(I)Pregnant women, women who might be pregnant, and breastfeeding women. (However, if "1. Do not use in the following conditions" is indicated, breastfeeding women shall be omitted.)

(II)People who are taking other common cold medicines, expectorant cough medicines, rhinitis medicines, anti-allergy medicines, pain killers or antipyretics medicines.

(III)People who are taking painkillers, antipyretics or common cold medicines containing acetaminophen.

(Must be indicated for preparations containing acetaminophen.)

(IV)People who have had peptic ulcers.

(Must be indicated for preparations containing salicylates.)

(V)People who take sedatives or sleeping medicine.

(Must be indicated for preparations containing antihistamine in Table 1 Category B.)

(VI)Adults aged 65 years and over or who have edema symptoms. [Must be indicated for preparations containing more than 1g Glycyrrhizae radix in Category H Group 2 (or more than 1g of the crude drug ingredient for extract).]

IV.**Other**

(I) Store properly to prevent children from accidentally taking this drug.

(II)Avoid direct sunlight.

(III)Do not exceed the stated dose.

(IV)Shake evenly before use, and use the measuring cup provided by the manufacturer to measure the dose.

(Must be indicated for solutions.)

(V)Do not take this medicine for more than seven days.

(VI)Excessive acetaminophen use may occur due to a desire for quicker or stronger analgesic effects, or due to repeatedly take medicines containing acetaminophen without knowing or noticing. However, taking more than 4,000 mg acetaminophen per day will cause liver damage.

(Must be indicated for preparations containing acetaminophen.)

(VII)Alcohol warnings: Do not take this medicine with alcoholic beverages, because acetaminophen (paracetamol) carries a risk of acute liver failure.

(Must be indicated for preparations containing acetaminophen.)

(VIII)Alcohol warnings: Do not take this medicine with alcoholic beverages; there are risks of acute liver failure and stomach bleeding.

(Must be indicated for preparations containing acetaminophen when they are in combination with salicylates.)

(IX)Alcohol warnings: Do not take this medicine with alcoholic beverages, because this may result in stomach bleeding.

(Must be indicated for preparations containing salicylates.)

(X)The medicine may cause drowsiness, so do not drive or operate dangerous machinery.

(Must be indicated for preparations containing antihistamine in Table 1 Category B.)

(XI)The medicine can not be used with alcoholic beverages.

(Must be indicated for preparations containing antihistamine in Table 1 Category B.)

(XII)Avoid taking medicines or drinks containing caffeine. Too much caffeine can cause nervousness, excitement and insomnia, and often results in tachycardia. To avoid dependence and liver and kidney damage, it must not be used for a long time.

(Must be indicated for preparations containing caffeine in Table 1 Category E.)

(XIII)Diabetes tests results will be affected while or after taking the medicine.

[Must be indicated for preparations containing more than 1.2 g Senegae radix in Category H Group 2 (or more than 1.2 g of the crude drug ingredient for extract).]

F. Dosage and Administration

I. Age group:

12 years of age and over.	"3 to 4 times a day" or "Once every 4 to 6 hours and do not exceed ◯ times within 24 hours." (Either description shall be indicated.)
Children 9 to less than 12 years of age.	1/2 of adult dosage.
Children 6 to less than 9 years of age.	1/3 of adult dosage.
Children under the age of 6 years.	Consult your doctor.

II.Dosage and Administration of day and night formula (Either description shall be indicated.)

Formula / Times	Three times a day	Four times a day
Day formula	Twice a day Take after breakfast and lunch.	Three times a day Take after breakfast, lunch and dinner.
Night formula	Once a day after dinner	Once a day before bed

III. Better taken within 30 minutes after meal.

(Must be indicated for preparations containing salicylates.)

G. Warnings

I. After taking the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

Body part	Side effects
Skin	Rash and redness.
Digestive organs	Nausea, vomiting, loss of appetite.
Nervous system	Dizziness, tinnitus.
Other	Sore throat, rapid heartbeat, difficulty in urination, or blurred vision.

II. After taking the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Any discomfort occurs.

(II) Cough lasts for more than a week, or high fever, purulent sputum, rash or persistent headache occurs.

(III) Symptoms are not alleviated, or symptoms continue followed by fever, or fever continues for three days.

(IV) Sore throat lasts for more than two days and is accompanied by high fever, headache, nausea or vomiting.

(V) Excessive use [more than 4,000 mg acetaminophen per day], or the following symptoms occur after taking this medicine: Gastrointestinal discomfort, anorexia, nausea, vomiting, paleness and sweating.

(Must be indicated for preparations containing acetaminophen.)

(VI)Allergic reactions, such as Swelling of face, mouth or throat; difficulty breathing; urticaria; rash or other skin irritation; itching and vomiting.

(Must be indicated for preparations containing acetaminophen.)

(VII)A decrease in urine output, swelling of the face or hands and feet, heavy eyelids, stiff hands, elevated blood pressure or headache. [Must be indicated for preparations containing more than 1g Glycyrrhizae radix in Category H Group 2 (or more than 1g of the crude drug ingredient for extract).]

Table 2 Combination rules and combination coefficients (Group I)

Active ingredient			Group I preparation				Notes	
			Combination rules	Combined with one ingredient from the same Category/Group	Combined with at least two ingredients from the same Category/Group			
				Combination coefficient	Combination coefficient	Lower limit for the daily dose of each ingredient		
Category A	Antipyretic and analgesic ingredients		◎	1/2≦ ≦1	1/2≦ ≦1	1/5	● Group I preparations should contain at least one, and at most two main essential composing ingredients can be used in combination at the same time. ● When Group I preparations are used in combination with acetaminophen or other active ingredients in Category A, the maximum daily dose used for calculation is 900mg.	
Category B	Antihistamine		△	1/2≦ ≦1			Can be combined with at most one ingredient.	The formula for Group I preparations should contain at least one main optional composing ingredient (△).
Category C	Group 1	Antitussive ingredient	△	1/2≦ ≦1			Can be combined with at most one ingredient.	
	Group 2	Expectorant	△	1/2≦ ≦1			Can be combined with at most one ingredient.	
Category D	Group 1	Decongestant	△	1/2≦ ≦1			● Can be combined with at most one ingredient (the ingredients in Category D Groups 1 and 2 cannot be used together). ● When the preparation is in combination with the ingredients in Category E, the sum of the ratio of the daily dose to the maximum daily dose of each ingredient in Categories D and E can not be greater than 3/2. ● Cannot be used in combination with the ingredients in Category H Group 1.	
	Group 2	Bronchodilator						

Category E	Caffeine		○	1/5≦ ≦1			● Can be combined with at most one ingredient.
Category F	Acidity neutralization		○	1/5≦ ≦1	1/2≦ ≦1	1/5	
Category G	Group 1	Vitamin B_1	○	Based on Table 1	≦1	Based on Table 1	● "From Table 1": Based on the upper and lower limits of maximum daily dose stipulated in Table 1.
	Group 2	Vitamin B_2	○	Based on Table 1	≦1	Based on Table 1	
	Group 3	Vitamin C	○	Based on Table 1	≦1	Based on Table 1	
	Group 4	Hesperidine	○	Based on Table 1			
Category H	Group 1	Crude drug ingredient	○	1/10≦ ≦1			● When the preparation is in combination with the ingredients in Category E, the sum of the ratio of the daily dose to the maximum daily dose of each ingredient in Category E and Category H Group 1 may not be greater than 3/2. ● Cannot be used in combination with ingredients from Category D.
	Group 2		○	1/10≦ ≦1	≦1	1/10	
	Group 3		○	1/10≦ ≦1	≦1	1/10	
	Group 4		○	1/10≦ ≦1	≦1	1/10	
Notes			● When the preparations contain oral solutions (including syrup) with antipyretic and analgesic ingredients, the maximum daily dose of each active ingredient used for calculation is 1/2 of the amounts specified in Table 1.				

◎: Main essential composing ingredients △: Main optional composing ingredients ○: Optional composing ingredients ×: Non-composing ingredient

Table 2 Combination rules and combination coefficients (Group II)

Active ingredient			Group II preparation				Notes	
			Combination rules	Combined with one ingredient from the same Category/Group	Combined with at least two ingredients from the same Category/Group			
				Combination coefficient	Combination coefficient	Lower limit for the daily dose of each ingredient		
Category A	Antipyretic and analgesic ingredients		◎	1/2≦≦1	1/2≦≦1	1/5	Can be combined with at most two ingredients;	Must must contain the main essential composing ingredients from at least two different categories
Category B	Antihistamine		◎	1/2≦≦1			Can be combined with at most one ingredient.	
Category C	Group 1	Antitussive ingredient	◎	1/2≦≦1			Can be combined with at most one ingredient.	
	Group 2	Expectorant	◎	1/2≦≦1			Can be combined with at most one ingredient.	
Category D	Group 1	Decongestant	◎	1/2≦≦1			● Can be combined with at most one ingredient (the ingredients in Category D Groups 1 and 2 cannot be used together). ● When the preparation is in combination with the ingredients in Category E, the sum of the ratio of the daily dose to the maximum daily dose of each ingredient in Categories D and E may not be greater than 3/2.	
	Group 2	Bronchodilator						
Category E	Caffeine		○	1/5≦≦1			● If used in combination with ingredients from Category E, the formulation basis used by one of the ten advanced countries must be submitted as evidence. ● Can be combined with at most one ingredient. ● When used in combination with the Group II preparations, the maximum daily dose used for calculation should follow the amount specified for Group I in Table 1.	

Category F	Acidity neutralization		○	1/5≦≦1	1/2≦≦1	1/5	●If used in combination with ingredients from Category F, the formulation basis used by one of the ten advanced countries must be submitted as evidence. ●When used in combination with the Group II preparations, the maximum daily dose used for calculation should follow the amount specified for Group I in Table 1.
Category G	Group 1	Vitamin B_1	○	Based on Table 1	≦1	Based on Table 1	● "Based on Table 1": Based on the upper and lower limits of maximum daily dose stipulated in Table 1. ● When used in combination with the Group II preparations, the maximum daily dose used for calculation should follow the amount specified for Group I in Table 1.
	Group 2	Vitamin B_2	○	Based on Table 1	≦1	Based on Table 1	
	Group 3	Vitamin C	○	Based on Table 1	≦1	Based on Table 1	
	Group 4	Hesperidine	○	Based on Table 1			
Category H	Group 1	Crude drug ingredient	×				Not applicable
	Group 2		×				
	Group 3		×				
	Group 4		×				
Notes			● When the preparations contain oral solutions (including syrup) with antipyretic and analgesic ingredients, the maximum daily dose of each active ingredient used for calculation is 1/2 of the amounts specified in Table 1.				

◎: Main essential composing ingredients ○: Optional composing ingredients ×: Non-composing ingredient

Table 2 Combination rules and combination coefficients (Group III)

Active ingredient			Group III preparations				Notes
			Combination rules	Combined with one ingredient from the same Category/Group	Combined with at least two ingredients from the same Category/Group		
				Combination coefficient	Combination coefficient	Lower limit for the daily dose of each ingredient	
Category A	Antipyretic and analgesic ingredients		×				Cannot be composed i
Category B	Antihistamine		◎	1/2≦≦1			Can be combined with
Category C	Group 1	Antitussive ingredient	◎	1/2≦≦1			Can be combined with
	Group 2	Expectorant	◎	1/2≦≦1			Can be combined with
Category D	Group 1	Decongestant	◎	1/2≦≦1			● Can be combin ingredient (the ingre Groups 1 and 2 cannot ● Cannot be used ingredients in Categor
	Group 2	Bronchodilator					
Category E	Caffeine		○	1/5≦≦1			● Can be combined ● Can only be used B (antihistamine) or C ● If is used in com Category H Group 1, dose of Category E (ca
Category F	Acidity neutralization		○	1/5≦≦1	≦1	1/5	
Category G	Group 1	Vitamin B_1	×				Cannot be composed i
	Group 2	Vitamin B_2	×				
	Group 3	Vitamin C	×				

	Group 4	Hesperidine	×				
Category H	Group 1	Crude drug ingredient	○	1/10≦ ≦1			● Cannot be used in combination with the ingredients in Category D.
	Group 2		○	1/10≦ ≦1	≦1	1/10	
	Group 3		○	1/10≦ ≦1	≦1	1/10	
	Group 4		×				Cannot be composed in the preparation
Notes							

◎: Main essential composing ingredients ○: Optional composing ingredients ×: Non-composing ingredient

Antitussive and expectorant drug products

A. Scope

The guideline applies to the preparations administered orally for the purpose of antitussive and expectorant effect.

B. Active ingredient

I .Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the maximum single dose and the maxmum daily dose for each active ingredient in Categories A and B.

Table 1. Active ingredient and dose

Category	Group	Active ingredient	Maximum single dose (mg)	Maximum daily dose (mg)
A		Carbetapentane citrate (Pentoxyverine)	20	60
		Chlophedianol hydrochloride	25	100
		Cloperastine hydrochloride	20	60
		Dextromethorphan hydrobromide	20	60
		Tipepidine citrate	20	60
		Tipepidine hibenzate	25	75
		Noscapine	20	60
		Noscapine hydrochloride	20	60
B	1	Guaifenesin (Guaiacol glyceryl ether)	200	1200
		Potassium cresolsulfonate	90	270
		Bromhexine hydrochloride	8	24
	2	Potassium guaiacolsulfonate	90	270
	3	Acetylcysteine	200	600

II. Combination rules (see Table 2)

(I) Essential composing ingredients:

1. The active ingredients in Category A and Category B Groups 1 and 3 of Table 1. The formula must contain at least one essential composing ingredient.
2. The ingredients in Category A and Category B Group 1 can be used in combination with at most one active ingredient.

(II) Optional composing ingredients:

1. The active ingredients in Category B Group 2 of Table 1, which can be used in combination with the essential composing ingredients in Category A.
2. The ingredients in Category B Group 2 must not be used in combination with the essential composing ingredient in Category B Group 1.

(III) Acetylcysteine in Category B Group 3 of Table 1 is limited to single-ingredient preparation only.

III. Combination dose of active ingredients: (see Table 2)

(I) The one-time maximum dose and daily maximum dose of each active ingredient in Table 1 Category A and Category B must not exceed the maximum single dose and maximum daily dose stipulated in Table 1.

(II) The combination coefficient for composing ingredients in each category should be between 1 and 1/2.

(III) Combination coefficient = X/mX

X: The daily dose of composing ingredient x in Category A (or Category B).

mX: The maximum daily dose of composing ingredient x in Category A (or Category B).

Table 2 Combination rules and combination coefficients

Active ingredient	Combination rules	Combined with one ingredient from the same Category	Notes
		Combination coefficient	

Category A		Antitussive ingredient	◎	1/2≦ ≦1	Can be used in combination with at most one ingredient.
Category B	Group 1	Expectorant	◎	1/2≦ ≦1	•Can be used in combination with at most one ingredient. •The ingredients in Category B Groups 1 and 2 may not be used in combination with each other. •Acetylcysteine in Category B Group 3 is single-ingredient preparation only.
	Group 2	Expectorant	○	1/2≦ ≦1	
	Group 3	Sputum dissolving ingredient	◎	1/2≦ ≦1	

◎: Essential composing ingredient ○: Optional composing ingredients

C. Dosage form:

Limited to tablets, film coated tablets, sugar coated tablets, capsules, soft capsules, oral solutions, syrups, powders, powders for solution, powders for syrup, granules for internal use, granules for syrup, and fine granules.

D. Use (indication):

When the preparation contains active ingredients in the Categories in Table 3, the indications can also include the following.

Table 3 Indications

Category	Group	Composing ingredients	Indication(s)
A		Antitussive ingredients	Antitussive
B	1*1	Expectorant ingredients or sputum dissolving	Expectorant
	2		
	3		Reduces the viscosity of

		ingredients	respiratory mucosal secretions

*1. If the composing ingredients contain bromhexine hydrochloride in Category B Group 1, the indication can be indicated as "expectorant and reduces the viscosity of respiratory mucosal secretions."

E. Precautions:

I. **Do not use in the following conditions:**

(I) People who are allergic to the ingredients of this product.

(II) People who are taking monoamine oxidase inhibitors (MAOIs) or selective serotonin reuptake inhibitors (SSRIs). (Must be indicated for preparations containing dextromethorphan.)

II. Under the following conditions, consult your doctor before use:

(I) People with cough or phlegmy cough caused by smoking, asthma or chronic obstructive pulmonary diseases (chronic bronchitis, emphysema, etc.).

(II) Children under the age of 3 years.

(III) Children under the age of 6 years.
(Must be indicated for preparations containing chlophedianol hydrochloride.)

(IV) People with bronchial asthma or respiratory insufficiency.
(Must be indicated for preparations containing acetylcysteine.)

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Pregnant women, women who might be pregnant, and breastfeeding women.

(II) Adults aged 65 years and over.

(Must be indicated for preparations containing acetylcysteine.)

IV. Other:

(I) Store properly to prevent children from accidentally taking this product .

(II) Avoid direct sunlight.

(III) Do not exceed the stated dose.

(IV) Shake evenly before use, and use the measuring cup provided to measure the dose.

(Must be indicated for solutions.)

(V) The medicine must not be used with alcoholic beverages.

(VI) This product will cause an increase in bronchial secretions, which must be carefully observed after use. If the secretions cannot be eliminated by coughing, it is recommended to use appropriate methods such as a change of posture, manual tapping or machine suction.

(Must be indicated for preparations containing acetylcysteine)

F. Dosage and Administration

Age	Dose
Adults and children aged 12 years and over.	Three to four times a day. Expectorant (guafenesin single-ingredient preparations) 4 to 6 times a day and do not take more frequently than every 4 hours.
Children 6 to less than 12 years of age.	1/2 of adult dosage.
Children 3 to less than 6 years of age.	1/4 of adult dosage.

Children under the age of 3 years.	Consult your doctor.

G. Warnings:

I. After taking the medicine , if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Any discomfort occurs.

(II) Fever, rash, persistent headache and cough that last for more than one week, or recurrence.

(III) Digestive tract: Feelings of discomfort such as nausea, vomiting, loss of appetite, or slight sulphur smell.

(Must be indicated for preparations containing acetylcysteine .)

(IV) Skin: Allergic symptoms such as rash.

(Must be indicated for preparations containing acetylcysteine.)

(V) Other: Bloody sputum, aversion to cold, fever, runny nose or inflammation in the mouth.

(Must be indicated for preparations containing acetylcysteine .)

Topical Antimicrobial and Antiseptic drug products

A. Scope

This guideline applies to antimicrobial and antiseptic preparations for external use .

B. Active ingredients

I. Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the maximum dose or dose limit for each active ingredient in Categories A, B, C and D.

Table 1. Active ingredient and dose

Category	Group	Active ingredient	Dose limit
A. Antibiotics	1	Bacitracin	400 unit/g and 500 unit/g
		Bacitracin (as Zinc)	400 unit/g and 500 unit/g (potency)
		Neomycin (as Sulfate)	3 mg/g and 3.5 mg/g (potency)
		Polymyxin B (as Sulfate)	5,000 unit/g, 8,000 unit/g and 10,000 unit/g (potency)
	2	Tetracycline Hydrochloride	30mg/g
Category	Group	Active ingredient	Dose limit
B. Local Antiseptics	1	Nitrofurazone	0.2% and 0.5% ointment
		Sulfadiazine	5%
	2	Benzalkonium Chloride	0.05 ~ 0.15%
		Benzethonium Chloride	0.1 ~ 0.5%
	Group	Active ingredient	Maximum dose

B. Local Antiseptics	3	Povidone-Iodine	1% potency iodine
		Cresol	1.5%
		Chloroxylenol	0.3% cream 5% solution for external use
		Terpineol	0.01% solution for external use
		Cetrimide	15% solution for external use
		Cetrimonium Bromide	3% solution for external use
		Chlorhexidine Gluconate	1.25%
Category	Group	Active ingredient	Dose limit
C. Local Anesthetics		Dibucaine	0.05 ~ 1 %
		Dibucaine Hydrochloride	
		Lidocaine	0. 5 ~ 4 %
		Lidocaine Hydrochloride	
		Pramoxine Hydrochloride	0.5 - 1 %
Category	Group	Active ingredient	Maximum dose
D. Other		Urea	10%
		Zinc Oxide	10%

II. Combination rules (see Table 2)

(1) Topical antibiotic drug products

1. Essential composing ingredients: The active ingredients in Category A of Table 1. The formula must contain at least one essential composing ingredient.

2. Optional composing ingredients: The active ingredients in Categories C and D of Table 1, which can be used in combination with essential composing ingredients in Category A.
3. The active ingredients in Category A of Table 1 can be used in combination with at most three active ingredients.
4. Bacitracin and Bacitracin (as Zinc) in Category A Group 1 of Table 1cannot be used together at the same time.
5. Tetracycline Hydrochloride in Category A Group 2 of Table 1 is limited to single-ingredient preparation only.
6. The active ingredients in Category C of Table 1 can be used in combination with at most one active ingredient.

(II) Topical antiseptic drug products

1. Essential composing ingredients: The active ingredients in Category B of Table 1. The formula must contain at least one essential composing ingredient.
2. Optional composing ingredients: The active ingredients in Categories C and D of Table 1, which can be used in combination with essential composing ingredients in Category B.
3. The active ingredients in Category B of Table 1 can be used in combination with at most two active ingredients.
4. Nitrofurazone and Sulfadiazine in Category B Group 1 of Table 1 can only be used in combination with the ingredients in the same Group or with Zinc oxide in Category D.
5. Povidone-Iodine in Category B Group 3 of Table 1 is limited to single-ingredient preparation only.
6. The active ingredients in Category C of Table 1 can be used in combination with at most one active ingredient.

III. Combination dose of active ingredients (see Table 2)

(I) The dose of each active ingredient in Category A Groups 1 and 2, Category B Groups 1 and 2, and Category C of Table 1 is as a fixed dose or dose range.

(II) When the formula contains an ingredient in Category B Group 3 of Table 1:

1. The combination coefficient for composing ingredients should be between 1 and 1/2.

2. Combination coefficient = X/mX

X: The dose of the composing ingredient x in Category B Group 3

mX: The maximum dose of the composing ingredient x in Category B Group 3

(III) When the formula contains the ingredients in Category D of Table 1:

1.The combination coefficient of the ingredients in that Group should be between 1 and 1/10.

2. Combination coefficient = X/mX

X: The dose of the composing ingredient x in Category D

mX: the maximum dose of the composing ingredient x in Category D

(IV) Calculation of maximum dose for Table 1: Unless otherwise stipulated in Table 1, the concentration of solutions for external use, lotions, aerosols for external use, sprays for external use and spray powders for external use should be calculated in W/V %, and other dosage forms shall be expressed in W/W%.

Table 2 Combination rules and combination coefficients

Active ingredient	Combination rules		Combination coefficient (individual ingredient)	Notes
	Topical antimicrobial drug products	Topical antiseptic drug products		

Category A		Antibiotics	◎	x	—	● The ingredients in Category A Group 1 can be used in combination with at most three ingredients. ●Bacitracin and Bacitracin (as zinc) in Category A Group 1 cannot be used together at the same time. ● Tetracycline hydrochloride in Category A Group 2 is for single-ingredient preparations only.
Category B	Group 1	Local antiseptics	x	◎	—	● The ingredients in Category B can be used in combination with at most two ingredients. ● Nitrofurazone and Sulfadiazine in Table 1 Category B Group 1 can only be used in combination with the ingredients in the same Category or with Zinc oxide in Category D. ● Povidone-Iodine in Category B Group 3 is for single-ingredient preparations only.
	Group 2				—	
	Group 3				1/2≦ ≦1	
Category C		Local anesthetics	○	○	—	●Can be combined with at most one ingredient.
Category D		Other	○	○	1/10≦ ≦1	-

◎: Essential composing ingredients ○: Optional composing ingredients x: Non-composing ingredient

C. Dosage form

I. Limited to creams, ointments, gels for external use, lotions, solutions for external use, powders for external use, emulsions, aerosols for external

use, sprays for external use, spray powders for external use, and tinctures.

II. For the ingredients with dosage forms indicated in Table 1, they can only be present as the indicated dosage forms.

D. Use (indication) and function

I. Indications for topical antimicrobial drug products: Urgent treatment, prevention of infection caused by skin trauma (such as knife wounds, stab wounds, scratches, abrasions, or minor burns), or slowing down infection of wounds.

II. Indication for topical antiseptic drug products: Urgent wound treatment of abrasions, cuts, stab wounds, scratches or [primary care of burns]*, and washing, disinfection, or sterilization around wounds to prevent wound infection.

*The symptom description [primary care of burns] is limited to the preparation containing ingredients of Category B Group 1.

(Creams, ointments, gels for external use, emulsions, powders for external use and spray powders for external use have no cleaning effects.)

III. The function of optional composing ingredients (can be indicated in the product insert as required by the composing ingredients)

Category	Function
C	Contains ingredients that can temporarily relieve pain and itching caused by skin irritation.
D	Contains ingredients that can temporarily relieve skin irritation.

E. Precautions

I. Do not use in the following conditions:

People who are allergic to the ingredient(s) of this product.

II. Under the following conditions, consult your doctor before use:

(I) Children under the age of 3 years.

(II) Deep skin tissue infections or large-area wounds, animal bites, or severe burns.

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Children, pregnant women, women who might be pregnant, and breastfeeding women.

IV. Other:

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III) Do not exceed the stated dose or number of uses.

(IV) When the area to be applied to or the surrounding area is dirty, clean first and then apply the drug.

(V) Wash hands thoroughly before and after using this drug .

(VI) This drug is for external use only and cannot be taken orally, nor used around the eyes, mucous membranes (such as the mouth, nose, vagina, scrotum or genital area), nor areas with eczema, ulceration, cracks or severe trauma.

(VII) Be careful not to get this drug in the eye. If contact occurs, rinse eyes immediately with water or warm water and see an ophthalmologist right away.

(VIII) Do not use this drug on a large body surface (an area as large as your two palms).

(IX) After application, keep the area applied to breathe. Do not cover it to avoid side effects.

(X) The following shall be indicated on the external containers or external packages of flammable solutions for external use: Keep away from fire sources.

(XI) Stains clothes.

(Must be indicated for preparations containing Tetracycline Hydrochloride.)

(XII) Do not use along with soap, to avoid loss of effect. (Must be indicated for preparations containing ingredients in Category B Group 2.)

(XIII) Before use, must be diluted in accordance with instructions, to prevent the skin from burning.

(Must be indicated for preparations containing Chlorhexidine Gluconate.)

(XIV) Avoid contact with the external auditory canal. May cause deafness when this drug flows into the middle ear from an eardrum rupture.

(Must be indicated for preparations containing Chlorhexidine Gluconate.)

(XV) Systemic absorption is possible for this drug. Therefore, repeated use may result in hypothyroidism in newborns, and goiter and hypothyroidism in pregnant women, fetuses or breast-feeding women.

(Must be indicated for preparations containing Povidone-Iodine.)

(XVI) This drug may stain the skin and clothes.

(Must be indicated for preparations containing Povidone-Iodine.)

(XVII) Massive use must be avoided to prevent systemic absorption. Death has been reported.

(Must be indicated for preparations containing local anesthetics in Category C.)

(XVIII) Do not use for more than 7 days.

(Must be indicated for preparations containing antibiotics.)

F. Dosage and Administration

I. Topical antimicrobial drug products:

1-3 times a day.	After local cleaning, apply (sprinkle or spray) an appropriate amount on affected area, and cover with sterile gauze or bandage when needed.

II. Topical antiseptic drug products:

Several times a day.	Apply (sprinkle or spray) an appropriate amount on affected area directly, or dab on with gauze pad or absorbent cotton.

G. Warnings

I. After applying the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

(I) The following information must be indicated for preparations containing antibiotics:

Body part	Side effects
Skin	Allergic dermatitis such as rash.
Ear	Ototoxicity*

Kidney	Nephrotoxicity*

* Must be indicated for preparations containing Neomycin.

(II) The following information must be indicated for preparations containing Chlorhexidine:

Body part	Side effects
Skin	Sense of irritation, sensitive skin, allergic reactions.

(III) The following information must be indicated for preparations containing local anesthetics from Category C:

Body part	Side effects
Skin	Local burning sensation, tingling and allergic reactions.

II. After applying the medicine , if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Discomfort other than that mentioned above.

(II) After seven days of use on the same area, feeling the condition has not improved or has worsened.

(III) Symptoms such as urticaria, edema, chest tightness, pale appearance, cold hands or feet, cold sweat, or difficulty breathing. (Must be indicated for preparations containing Povidone-Iodine.)

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Topical Antifungal drug products

A. Scope

This guideline applies to preparations for external use for treatment of superficial fungal infection of the skin, such as tinea pedis (athlete's foot), tinea corporis, tinea cruris, tinea versicolor, onychomycosis, tinea capitis and treatment of adjuvant therapy for dandruff caused by fungal infection.

B. Active ingredients

I. Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the maximum dose and dose limit for each active ingredient in Categories A, B and C.

Table 1. Active ingredient and dose

Category	Group	Active ingredient	Maximum dose
A. Topical antifungal preparation	1	Clotrimazole	1%
		Econazole nitrate	1%
		Isoconazole nitrate	1%
		Miconazole nitrate	2%
	2	Undecylenic acid and derivatives	25 % of Total
	3	Tolnaftate	2%
	4	Active ingredient	Dose limit
		Amorolfine	0.5% cream
			5% toe (finger) nail lacquer
		Ciclopirox olamine	1%
		(Ciclopirox ethanolamine salt)	1.5% shampoo
		Ketoconazole	1% or 2% shampoo
		Terbinafine hydrochloride	1%

Table 1. Types of active ingredients

Category	Group	Active ingredient	Maximum dose
B. Antipruritic preparation	1	Chlorpheniramine maleate	0.5%
		Diphenhydramine	1%
		Diphenhydramine hydrochloride	2%
		Diphenhydramine salicylate	2%
		Diphenylpyraline hydrochloride	0.2%
	2	Crotamiton	10%
C. Other	1	Zinc oxide	10%
	2	Urea	10%
		Salicylic acid	2%
	3	Camphor	4%
		Menthol	3%
		Menthol oil	0.5%
		Thymol	2.5%

II. Combination rules:

(I) Essential composing ingredients: The active ingredients in Category A Groups 1, 2, 3, and 4 of Table 1. The formula must contain at least one essential composing ingredient.

(II) Optional composing ingredients: The active ingredients in Category B Groups 1 and 2, and Category C Groups 1, 2 and 3 of Table 1, which can be used in combination with the essential composing ingredients in Category A.

(III) Unless otherwise stipulated, the active ingredients in Category A of Table 1 can be used in combination with at most one active ingredient.

(IV) Econazole nitrate and Isoconazole nitrate in Category A Group 1 of Table 1, and Amorolfine, Ciclopirox olamine, Ketoconazole and Terbinafine hydrochloride in Category A Group 4 are limited to single-ingredient preparations only.

(V) Undecylenic acid in Category A Group 3 of Table 1 can be combined with its salt base as a compound preparation.

(VI) The active ingredients in Category B Group 1 and Category C Groups 2 and 3 of Table 1 can be used in combination with at most one active ingredient from each Group.

(VII) When the ingredients in Category C Group 3 are used in combination, they can be the active ingredients (optional composing ingredients) or excipients. However, when they are used as active ingredients (optional composing ingredients), relevant technical information shall be attached in accordance with the stipulations of the Regulations for Registration of Medicinal Products.

III. Combination dose of active ingredients:

(I) Active ingredients in Category A Groups 1, 2 and 3 of Table 1:

1. The combination coefficient of the composing ingredients in Category A Groups 1, 2 and 3 must be between 1 and 1/2.
2. If the formula contains Undecylenic acid and its salt base, their combination dose shall be calculated together.
3. Combination coefficient = X/mX

X: The dose of the composing ingredient x in Category A Group 1 (Group 2 or Group 3)

mX: The maximum dose of the composing ingredient x in Category A Group 1 (Group 2 or Group 3)

(II) The doses of Amorolfine, Ciclopirox olamine, Ketoconazole and Terbinafine hydrochloride indicated in Category A Group 4 of Table 1 are fixed doses.

(III) When the formula contains the ingredients in Category B Groups 1 or 2 or Category C Groups 1, 2 or 3 of Table 1:

1.The combination coefficient of the ingredients in that Group must be between 1 and 1/10.

2. Combination coefficient = X/mX

X: The dose of the composing ingredient x in Category B Group 1 (Category B Group 2 or Category C Groups 1, 2 or 3)

mX: The maximum dose of the composing ingredient x in Category B Group 1 (Category B Group 2 or Category C Groups 1, 2 or 3)

(IV) Calculation of maximum dose concentration for Table 1: The concentration of solutions for external use, lotions, aerosols for external use, sprays for external use and spray powders for external use must be calculated in W/V %, and other dosage forms shall be expressed in W/W%.

C. Dosage form

I. Limited to cream, ointment, gel for external use, lotion, solution for external use, powder for external use, emulsion, suspension solution for external use, aerosol for external use, spray for external use and spray powder for external use.

II. For the ingredients with dosage forms indicated in Table 1, they can only be present as the indicated dosage forms.

III. Preparations containing 1% Ciclopirox olamine in Category A Group 4 of Table 1are limited to cream, ointment and lotion.

IV. Preparations containing Terbinafine hydrochloride in Category A Group 4 of Table 1 are limited to cream, solution for external use, gel for external use and spray for external use.

V. This guideline does not apply to preparations for external use containing Terbinafine hydrochloride in Category A Group 4 of Table 1 for single application treatment.

D. Use (indication) and function

I. Indications for general preparations: Treating superficial fungal infection of the skin, such as tinea pedis (athlete's foot), tinea corporis, tinea cruris and tinea versicolor.

II. The stipulations for indications of preparations containing special ingredients (or in special dosage forms) are as follows:

(I) Indications for shampoos containing Ketoconazole or Ciclopirox olamine: Auxiliary agent for treating and reducing dandruff caused by fungal infection

(II) Indications for creams containing 0.5% Amorolfine: Treating superficial fungal infection of the skin, such as tinea pedis (athlete's foot), tinea corporis, tinea cruris.

(III) Indications for toe (finger) nail lacquer containing 5% Amorolfine: Treating mild fungal nail infections affecting the upper half or sides of the nail caused by dermatophytes, yeasts or molds.

III. The function of optional composing ingredients (can be indicated in the product insert as required by the composing ingredients.)

Category	Group	Function
A	4	The pharmacological effects of Amorolfine can follow the original license holder's product insert.
B	1, 2	Contains ingredients that can temporarily relieve skin itchiness.
C	1	Contains ingredients that can temporarily relieve skin irritation.
C	2	Contains exfoliation ingredients.
	3	Contains ingredients that can temporarily relieve pain.

E. Precautions

I. **Do not use in the following conditions**:

(I) People who are allergic to the ingredient(s) of this product.

II.**Under the following conditions, consult your doctor before use**:

(I) Children under the age of 3 years.

(II) Children under the age of 12 years.

(Must be indicated for toe (finger) nail lacquer preparations containing Amorolfine or preparations containing Terbinafine hydrochloride.)

(III) Deep skin tissue infections.

(IV) Diagnosis by a dermatologist is required before first time use of this medicine.

(Must be indicated for toe (finger) nail lacquer preparations containing Amorolfine.)

III.Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Children, pregnant women, women who might be pregnant, and breastfeeding women.

(II) People who are undergoing treatment by a doctor.

(III) Where the affected area is on the face.

(IV) Where there is pus at the affected part.

IV. Other :

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III) Do not exceed the stated dose or number of uses.

(IV) When the area to be applied to or the surrounding area is dirty, clean first and then apply the medicine.

(V) Wash hands thoroughly before and after using this medicine.

(VI) This drug is for external use only. Cannot be taken orally, nor used around the eyes, or mucous membranes (such as the mouth, nose, vagina, scrotum or genital area), nor areas with eczema, infiltration, ulceration, cracks or severe trauma.

(VII) Be careful not to get the medicine in the eye. If contact occurs, rinse eyes immediately with water or warm water and see an ophthalmologist right away.

(VIII) Do not use this medicine on a large body surface (an area as large as your two palms).

(Must be indicated for preparations Except for Shampoo preparations contain Ketoconazole and Ciclopriox olamine)

(IX) After application, keep the area applied to breathe. Do not cover it to avoid side effects.

(X) The course of treatment for a general mold infection is at least two weeks, depending on the degree and location of the infection. You

must complete the entire course of treatment when using this medicine.

(XI) Nail files used on the affected area cannot be used on healthy toe (finger) nails. Avoid using cosmetic nail varnish and artificial nails during treatment.

(Must be indicated for toe (finger) nail lacquer preparations containing Amorolfine.)

(XII) When the medicine is used continuously for more than three weeks, the likelihood of allergic contact dermatitis will increase. (Must be indicated for preparations containing antipruritic ingredients (Table 1 Category B Group 1))

(XIII) Large-scale and long-term use will cause Salicylic Acid reaction (tinnitus, dizziness, nausea, vomiting, etc.).

(Must be indicated for preparations containing Salicylic Acid.)

(XIV) Avoid contact with clothing, plastic, wood and metal.

(Must be indicated for preparations containing Salicylic Acid.)

(XV) The following shall be indicated on the external containers or external packages of flammable solutions for external use: Keep away from fire sources.

F. Dosage and Administration

I. General preparations:

Once to twice a day	Apply to the affected area evenly.

II. Preparations containing special ingredients (or in special dosage forms):

(I) Shampoos containing Ketoconazole or Ciclopirox olamine:

Twice a week,	at least three days apart. Do not use for more

	than four weeks.

(II) Toe (finger) nail lacquer containing 5% Amorolfine:

Once to twice a week	Apply the lacquer to the fingers and toes of the patient.

The following steps must be followed every time the product is used:

1. Carefully clean the toe (finger) nail before applying the Amorolfine toe (finger) nail lacquer for the first time. Use the disposable nail file that comes with this medicine to file the affected part of the toe (finger) nail as flat as possible (especially the nail surface). Be careful not to file the skin around the toe (finger) nail.

   Notes: The file used on the infected toe (finger) nails cannot be used on healthy toe (finger) nails.

2. Use an alcohol pad to wipe and clean the surface of the infected toe (finger) nails.
3. Dip the reusable applicator that comes with the medicine into the bottle of nail lacquer. The applicator must not wipe on the edge of the bottle.

   Notes: The applicator is used to provide a fixed dose of lacquer.

4. Use the applicator to apply the Amorolfine toe (finger) nail lacquer evenly over the entire surface of the nail.
5. Close the bottle immediately after use, to avoid evaporation of the lacquer.
6. Repeat steps 1, 2, 3, and 4 for each affected toe (finger) nail.
7. The lacquer will dry in about 3-5 minutes.

8. After use, clean the applicator and the edge of the bottle with alcohol pads used to clean the toe (finger) nails.

   When working with organic solvents (thinners or mineral spirits), wear non-permeable gloves to protect the Amorolfine lacquer on the toe (finger) nails.

   Continue to use this medicine and not interrupt, until the infection has cleared and health toe (finger) nails has grown back. The course of the treatment depends on the degree of infection, location, and growth rate of the toe (finger) nails. This usually takes 6 months for finger nails and 9 to 12 months for toe nails.

(Ⅲ) Creams containing 0.5% Amorolfine:

Once a day	(1) To be applied to affected skin areas following cleansing, every night. The treatment should be continued without interruption until cure, or for 3 to 5 days thereafter. (2) To treat a fungal infection should be continued for at least two to three weeks. With tinea pedis, up to six weeks of therapy may be necessary. The entire course of treatment must be completed.

(IV) Various preparations containing Terbinafine hydrochloride:

Dosage form	Dosage and Administration	
Cream for external use	Once a day Once to twice a day	Tinea pedis, tinea corporis and tinea cruris

		Tinea versicolor
Solution for external use	Once a day Twice a day	Tinea pedis and tinea cruris Tinea versicolor
Gel for external use	Once a day	Tinea pedis, tinea corporis, tinea cruris and tinea versicolor
Spray for external use	Once a day Twice a day	Tinea corporis, tinea cruris and tinea pedis Tinea versicolor

(V) Lotion or suspension solution for external use must be shaken well before use.

G. Warnings

I. After applying the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

(I) The following information must be indicated for preparations containing antifungal ingredients from Table 1 Category A:

Part	Side effects
Skin	Local skin irritation and burning sensation, and allergic dermatitis such as redness, swelling, blisters, peeling and itching.

(II) The following information must be indicated for preparations containing Amorolfine toe (finger) nail lacquer:

Part	Side effects
Around the toe (finger) nails	Mild and brief burning sensation

(III) The following information must be indicated for preparations containing Salicylic acid:

Part	Side effects
Skin	Erythema, itching and tingling
Other	Salicylic acid reaction (tinnitus, dizziness, nausea, vomiting, etc.).

II. After applying the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Discomfort other than that mentioned above.

(II) Feeling the condition has not improved or has worsened.

(III) Generally, symptoms will improve after 7 days treatment, two weeks for tinea cruris and tinea corporis, and four weeks for tinea pedis. If your symptoms have not improved after the above treatment time, stop using the medicine and seek medical advice immediately. Even if symptoms improve, but after stop using the medicine, the condition relapses, you must seek medical advice immediately.

(IV) There is no effect after three months of continuous use.

(Must be indicated for toe (finger) nail lacquer preparations containing Amorolfine.)

Topical Antipruritic and anti-inflammatory drug products

A. Scope

This guidelines applies to preparations for external use for temporarily relieve inflammation, swelling and itching caused by skin diseases, such as eczema, prurigo, diaper rash, mosquito/ insect bites, itchy skin and dermatitis.

B. Active ingredients

I. Active ingredient and dose :

(1) The active ingredients specified in Table 1 are applicable to this guideline.

(2) Table 1 stipulates the dose limit (or dose range) and maximum dose for each active ingredient in each category.

Table 1. Active ingredient and dose

Category	Group	Active ingredients	Dose limit (%)	Dosage form
A. Anti-inflammatory ingredients	Group 1	Dexamethasone	0.025-0.10	—
		Dexamethasone acetate	0.025-0.10	—
		Hydrocortisone	0.25-2.5	—
		Hydrocortisone acetate	0.1-2.5	—
		Methylprednisolone acetate	0.25	—
		Prednisolone	0.1-0.25	—
		Prednisolone acetate	0.25	—
		Prednisolone valerate acetate	0.15	—
	Group 2	Fluocinolone acetonide	0.01	solution

Category	Group	Active ingredient	Maximum dose (%)	Dosage form
B. Antihistamines		Chlorpheniramine maleate	1.0	—
		Diphenhydramine	1.0	—
		Diphenhydramine HCl	2.0	—
		Diphenylpyraline HCl	0.3	—
C		Crotamiton	10.0	—
D. Local anesthetic ingredients		Dibucaine	1.0	—
		Dibucaine HCl	0.5	—
		Lidocaine	3.0	—
		Lidocaine HCl	3.0	—
		Pramoxine HCl	1.0	—
E. Disinfectant		Isopropylmethylphenol	0.5	—
		Benzalkonium chloride	0.3	—
		Benzethonium chloride	0.1	—
		Chlorhexidine HCl	0.2	—
		Nitrofurazone	0.2	—
F. Other	Group 1	Zinc oxide	10.0	—
		Urea	10.0	—
	Group 2	Calamine	8.0	—
	Group 3	Methyl salicylate	5.0	—
	Group 4	d-Camphor	0.1-7.0	—
		dl-Camphor	0.1-7.0	—
	Group 5	Mentha oil	2.0	—

Category	Group	Active ingredient	Maximum dose (%)	Dosage form
F. Other	Group 5	dl-Menthol	0.1-5.0	—
		l-Menthol	0.1-5.0	—
	Group 6	Allantoin	1.0	—
	Group 7	Glycyrrhetic Acid	1.0	—
G. Vitamins	Group 1	Tocopherol	0.1-2.0	—
		Tocopherol acetate		—
	Group 2	Panthenol	5.0	—
	Group 3	Vitamin A oil	Vitamin A 5,000IU/g	—
		Retinol palmitate		—

II. Combination rules

(I) Products that use steroids in Category A Group 1 of Table 1as the main ingredient (see Table 2)

1. Essential composing ingredients: The active ingredients in Category A Group 1 of Table 1; the formula must contain at least one essential composing ingredient.
2. Optional composing ingredients: The active ingredients in Categories B, C, D, E, F and G of Table 1. Unless otherwise stipulated, these ingredients can be used in combination with the essential composing ingredients in Category A Group 1.
3. The active ingredients in Categories A, B, D, and E of Table 1 can be used in combination with at most one active ingredient in each category.

4. The active ingredients in Category F Groups 1, 4, and 5 and Category G Groups 1 and 3 of Table 1 can be used in combination with at most one active ingredient in each group.

(II) Products that use steroids in Category A Group 2 of Table 1 as the main ingredient (see Table 2)

1. Essential composing ingredients: The active ingredients in Category A Group 2 of Table 1; the formula must contain essential composing ingredients.
2. Optional composing ingredients: The active ingredients in Category B, Category D and Category F Group 1 of Table 1. Unless otherwise stipulated, these ingredients can be used in combination with the essential composing ingredients in Category A Group 2.
3. The active ingredients in Category B, Category D and Category F Group 1 of Table 1 can be used in combination with at most one active ingredient in each Category (Group).

(Ⅲ) Products that use antihistamines in Category B of Table 1 as the main ingredient (see Table 3)

1. Essential composing ingredients: The active ingredients in Category B of Table 1. the formula must contain at least one essential composing ingredient.
2. Optional composing ingredients: The active ingredients in Categories C, D, E, F and G of Table 1. Unless otherwise stipulated, these ingredients can be used in combination with the essential composing ingredients in Category B.
3. The active ingredients in Categories B, D and E of Table 1 can be used in combination with at most one active ingredient in each category.

4. The active ingredients in Category F Groups 1, 4, and 5 and Category G Groups 1 and 3 of Table 1 can be used in combination with at most one active ingredient in each Group.

(Ⅳ) Products containing Pramoxine HCl in Category D of Table 1, can only be used in combination with Hydrocortisone and Hydrocortisone acetate in Category A Group 1, Diphenhydramine HCl in Category B, and Category F Groups 3, 4 and 5.

(Ⅴ) When the ingredients in Category F Groups 4 and 5 are used in combination as topical antipruritic and anti-inflammatory drug products, they can be the active ingredients (optional composing ingredients) or excipients. However, when they are used as active ingredients (optional composing ingredients), relevant technical information shall be attached in accordance with the stipulations of the Regulations for Registration of Medicinal Products.

III. Combination dose of active ingredients:

(I) Products that use steroids in Category A Groups 1 and 2 as the main ingredient (see Table 2)

1. The concentration of each active ingredient in Category A Groups 1 and 2 of Table 1 is as fixed dose or a dose range.

2. When the formula contains the ingredients in Categories B and C, Category F Groups 1, 3, and 6, and Category G Group 2 of Table 1:

(1) The combination coefficient of the ingredients in that Category (Group) should be between 1 and 1/5.

(2) Combination coefficient = X/mX

X: The dose of the composing ingredient X in Category B (Category C, Category F Groups 1, 3, and 6, or Category G Group 2)

mX: The maximum dose of the composing ingredient x in Category B (Category C, Category F Groups 1, 3, and 6 or Category G Group 2)

3. When the formula contains the ingredients in Category D, Category E and Category F Group 7, or Category G Group 3 of Table 1:

(1) The combination coefficient of the ingredients in that Category (Group) should be between 1 and 1/10.

(2) Combination coefficient = X/mX

X: The dose of the composing ingredient X in Category D (Category E or Category F Group 7 and Category G Group 3)

mX: The maximum dose of the composing ingredient X in Category D (Category E or Category F Group 7 and Category G Group 3)

4. When the products contains the ingredients in Category F Group 4 or 5 and Category G Group 1 of Table 1, the combination amount shall follow the upper limit and lower limit stipulated in Table 1.

(II) Products that use antihistamines in Category B as the main ingredient (see Table 3)

1. Ingredient in Category B of Table 1:

(1) The combination coefficient of the composing ingredients in Category B should be between 1 and 1/2.

(2) Combination coefficient = X/mX

X: The dose of the composing ingredient X in Category B

mX: The maximum dose of the composing ingredient X in Category B

2. When the formula contains the ingredients in Category C, Category F Groups 1, 2, 3, or 6, and Category G Group 2 of Table 1:

(1) The combination coefficient of the ingredients in that Category (Group) should be between 1 and 1/5.

(2) Combination coefficient = X/mX

X: The dose of the composing ingredient X in Category C (Category F Groups 1, 2, 3, and 6, or Category G Group 2)

mX: The maximum dose of the composing ingredient X in Category C (Category F Groups 1, 2, 3, and 6, or Category G Group 2)

3. When the formula contains the ingredients in Category D, Category E and Category F Group 7, or Category G Group 3 of Table 1:

(1) The combination coefficient of the ingredients in that Category (Group) should be between 1 and 1/10.

(2) Combination coefficient = X/mX

X: The dose of the composing ingredient X in Category D (Category E or Category F Group 7 and Category G Group 3)

mX: The maximum dose of the composing ingredient X in Category D (Category E or Category F Group 7 and Category G Group 3)

4. When the preparation contains the ingredients in Category F Group 4 or 5 and Category G Group 1 of Table 1, the combination dose shall follow the upper limit and lower limit stipulated in Table 1.

(III) Calculation of maximum dose concentration for Table 1: The concentration of solutions for external use, lotions, liniments and sprays for external use should be calculated in W/V %, and other dosage forms shall be expressed in W/W%.

Table 2: Products that use steroids in Category A as the main ingredient

Ingredient			Combination rules		Combination coefficient (each ingredient)	Number of ingredients	
			Products that use ingredient in Category A Group 1 as the main ingredient	Products that use ingredient in Category A Group 2 as the main ingredient		Within Group	Within Category
Category A	Group 1	Corticosteroid	◎	X	—	1	1
	Group 2		X	◎	—	—	
Category B		Antihistamine	○	○	1/5≦ ≦1	—	1
Category C		Crotamiton	○	X	1/5≦ ≦1	—	—
Category D		Local anesthetic	○	○	1/10≦ ≦1	—	1
Category E		Disinfectant	○	X	1/10≦ ≦1	—	1
Category F	Group 1	Astringent	○	○	1/5≦ ≦1	1	—
	Group 2	Calamine	○	X	—	—	—
	Group 3	Methyl salicylate	○	X	1/5≦ ≦1	1	—
	Group 4	Camphor	○	X	—	1	—
	Group 5	Menthol	○	X	—	1	—
	Group 6	Allantoin	○	X	1/5≦ ≦1	—	—
	Group 7	Glycyrrhizic acid	○	X	1/10≦ ≦1	—	—
Category G	Group 1	Vitamin E	○	X	—	1	—
	Group 2	Panthenol	○	X	1/5≦ ≦1	—	—
	Group 3	Vitamin A	○	X	1/10≦ ≦1	1	—

◎: Essential composing ingredient ○: Optional composing ingredient X: Non-composing ingredient

Table 3: Products that use antihistamines in Category B as the main ingredient

Ingredient			Combination rules	Combination coefficient (each ingredient)	Number of ingredients	
					Within Group	Within Category
Category A		Corticosteroid	X	—	—	—
Category B		Antihistamine	◎	1/2≦ ≦1	—	1
Category C		Crotamiton	○	1/5≦ ≦1	—	—
Category D		Local anesthetic	○	1/10≦ ≦1	—	1
Category E		Disinfectant	○	1/10≦ ≦1	—	1
Category F	Group 1	Astringent	○	1/5≦ ≦1	1	—
	Group 2	Calamine	○	1/5≦ ≦1	—	—
	Group 3	Methyl salicylate	○	1/5≦ ≦1	1	—
	Group 4	Camphor	○	—	1	—
	Group 5	Menthol	○	As per dose range stipulated in Table 1.	1	—
	Group 6	Allantoin	○	1/5≦ ≦1	—	—

	Group 7	Glycyrrhizic acid	○	1/10≦ ≦1	—	—
Category G	Group 1	Vitamin E	○	—	1	—
	Group 2	Panthenol	○	1/5≦ ≦1	—	—
	Group 3	Vitamin A	○	1/10≦ ≦1	1	—

◎: Essential composing ingredient ○: Optional composing ingredient X: Non-composing ingredient

C. Dosage form

I. Limited to creams, ointments, topical gels, lotions, liniments, topical solutions and topical sprays.

II. For the ingredients with dosage forms indicated in Table 1, they can only be present as the indicated dosage forms.

D. Use (indications) and functions

I. Indications for Products that use steroids in Category A Group 1 as the main ingredient: Temporary relief of symptoms caused by skin diseases such as eczema, diaper rash, mosquito/ insect bites, itchy skin and dermatitis.

II. Indications for Products that use steroids in Category A Group 2 as the main ingredient: Temporary relief of symptoms caused by skin diseases such as eczema, prurigo and dermatitis.

III. Products that use antihistamines in Category B as the main ingredient: Temporary relief of symptoms caused by skin diseases such as diaper rash, mosquito/ insect bites, itchy skin and dermatitis.

IV. The functions of optional composing ingredients (can be indicated in the product insert as required by the composing ingredients.)

Category	Group	Function
C	—	Contains ingredients that can temporarily relieve itching.
D	—	Contains ingredients that can temporarily relieve pain and itching caused by skin irritation.
E	—	Contains local disinfectant ingredients.

F	1	Contains ingredients that can temporarily relieve skin irritation or soften keratin.
	2	Contains astringent ingredients.
	6	Contains astringent ingredients.
	7	Contains anti-inflammatory ingredients.

E. Precautions

I. Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product .

(II) Children under the age of 2 years.

(Must be indicated for liniments containing Menthol, Camphor or Methyl salicylate.)

(III) People who have been allergic or sensitive to aspirin or salicylic acid.

(Must be indicated for topical ointments containing Methyl salicylate.)

III. Under the following conditions, consult your doctor before use:

(I) Children under the age of 3 years.

(II) Deep skin tissue infections.

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Children, pregnant women, women who might be pregnant, and breastfeeding women.

(II) When this drug is to be used on the face.

IV. Other:

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III) Do not exceed the stated dose or number of uses.

(IV) When the area to be applied to or the surrounding area is dirty, clean first and then apply the drug.

(V) Wash hands thoroughly before and after using this drug.

(VI) This drug is for external use only. Cannot be taken orally, nor used around the eyes, mucous membranes (such as the mouth, nose, vagina, scrotum or genital area), nor areas with ulceration, cracks or severe trauma.

(VII) Be careful not to get the drug in the eye. If contact occurs, rinse eyes immediately with water or warm water and see an ophthalmologist right away.

(VIII) Do not use this drug on a large body surface (an area as large as your two palms).

(IX) After application, keep the area applied to breathe. Do not cover it to avoid side effects.

(X) Do not use this drug on areas other than the affected area, and do not use for preventive purposes.

(XI) This drug cannot be used continuously for more than 7 days.

(XII) The following information must be indicated for the anti-inflammatory product containing steroids in Category A:

1、Sometimes it is hard to distinguish skin fungal or bacterial infections from other dermatitis. Misuse of steroids will worsen the condition and make diagnosis and treatment difficult in the future.

2、Long-term use in children is more likely to cause Cushing's syndrome and adrenal dysfunction.

3、Long-term use of steroids on the face, armpits or groin areas tends to lead to local skin atrophy.

4、For tinea or other skin infections, an anti-infective agent must be used. Using steroids alone may worsen the condition.

(XIII) Massive use must be avoided to prevent systemic absorption. Death has been reported.

(Must be indicated for preparations containing local anesthetic preparations in Category D.)

(XIV) Do not use along with soap, to avoid loss of effect.

(Must be indicated for preparations containing Benzalkonium chloride and Benzethonium chloride in Category E Group 1.)

(XV) Avoid contact with the external auditory canal. May cause deafness when this drug flows into the middle ear from an eardrum rupture.

(Must be indicated for preparations containing Chlorhexidine in Category E Group 1.)

(XVI) Avoid contact with clothing, plastic, wood and metal.

(Must be indicated for products containing Methyl salicylate in Category F Group 3.)

(XVII) Do not use on a large area for a long period of time, to avoid symptoms of salicylic acid poisoning, such as difficulty breathing, sweating, hyperthermia, flushing, persistent tinnitus, and severe or persistent headache. Consult a physician or pharmacist before use.

(Must be indicated for preparations containing Methyl salicylate in Category F Group 3) (according to announcement No. 1051407990)

(XVIII) The following shall be indicated on the external containers or external packages of flammable topical solutions:

Keep away from fire sources.

F. Dosage and Administration

I. Dosage and Administration for products using steroids in Category A as the main ingredient:

2-4 times a day	Apply a thin layer to cover the affected area.

II. Dosage and Administration of Products that use antihistamines in Category B as the main ingredient:

Use when needed.	Apply an appropriate amount on the affected area.

G. Warnings

I. After applying the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

(I) The following information must be indicated for preparations containing steroids from Category A:

Body part	Side effects
Skin	Itching, tingling, erythema, skin infections, folliculitis, acne, over-hydrated skin, secondary infections, hirsutism, skin atrophy, miliaria and telangiectasia.
Systemic	Cushing's syndrome (such as moon face, weight gain, fatigue, high blood pressure, hirsutism, abnormal menstruation, abnormal personality, edema, polyuria, thirst, etc.). Secondary adrenal insufficiency (such as fatigue, weakness, nausea, vomiting, loss of appetite, weight loss, hypotension, abdominal pain, constipation or diarrhea).

(II) The following information must be indicated for preparations containing local anesthetic preparations from Category D:

Body part	Side effects
Skin	Local burning, tingling and allergic reactions.

(III) The following information must be indicated for preparations containing Methyl salicylate from Category F Group 3:

Body part	Side effects
Skin	Erythema, itching and tingling
Other	Salicylic acid reaction (tinnitus, dizziness, nausea, vomiting, etc.).

II. After applying the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Discomfort other than that mentioned above.

(II) After seven days of use, feeling the condition has not improved or has worsened .

Topical Acne drug products

A. Scope

This guidelines applies to preparations for external use for the treatment of acne vulgaris (acne, pimples).

B. Active ingredients

I. Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II)Table 1 stipulates the dose limit or maximum dose for each active ingredient in Categories A, B and C.

Table 1. Active ingredient and dose

Category	Group	Active ingredient	Dose limit
A	1	Benzoyl peroxide	2.5~10%
	2	Sulfur	3-10%
B		Resorcinol =(Resorcin, 1,3-Benzenediol)	2% (cannot be used in lotions)
Category	Group	Active ingredient	Maximum dose
C	1	l-Menthol	0.50%
	2	Camphor	0.30%

II. Combination rules (see Table 2):

(I) Essential composing ingredients: The active ingredients in category A of Table 1. The formula must contain at least one essential composing ingredient.

(II) Optional composing ingredients: The active ingredients in Category B and Category C Groups 1 and 2 of Table 1, which can be used in combination with the essential composing ingredients in Category A Group 2 as fixed-dose combination preparations.

(III) Benzoyl peroxide in Category A Group 1 is limited to single-ingredient preparation only.

(IV) Resorcinol in Category B can only be used in combination with Sulfur in Category A Group 2 as a fixed-dose combination preparation, and cannot be composed in lotion dosage form.

(V) When the ingredients in Category C are used in combination, they can be the active ingredients (optional composing ingredients) or excipients. However, when they are used as active ingredients (optional composing ingredients), relevant technical information shall be attached in accordance with the stipulations of the Regulations for Registration of Medicinal Products.

III. Combination dose of active ingredients (see Table 2):

(I) The concentration of each active ingredient in Category A Groups 1 and 2 and Category B of Table 1 is as a dose range or fixed dose.

(II) When the formula contains the ingredients in Category C Groups 1 and 2 of Table 1:

1.The combination coefficient of the composing ingredients should be between 1 and 1/2.

2. Combination coefficient = X/mX

X: The dose of the composing ingredient X in Category C Group 1 (Group 2)

mX: The maximum dose of the composing ingredient x in Category C Group 1 (Group 2)

(III) When Sulfur in Table 1 Category A Group 2 is used in combination with Resorcinol in Category B or Menthol in Category C Group 1 or Camphor in Group 2, the maximum dose limit is 8%.

(IV) Calculation of maximum dose concentration for Table 1: The concentration of solutions for external use, lotions, liniments must be calculated in W/V %, and other dosage forms shall be expressed in W/W%.

Table 2 Combination rules Combination coefficient

Active ingredient			Combination rules		Combination coefficient	Notes
A	1	Topical Acne drug products	◎	X	—	●The ingredient in Category A can only be used in combination with one ingredient. ●Benzoyl peroxide in Category A Group 1 is limited to single-ingredient preparation only. The dose ranges is limited from 2.5% to 10%. ● When sulfur in Category A Group 2 is used as a single-ingredient preparation, the dose ranges is limited from 3% to 10%. ● When Sulfur in Category A Group 2 is used in combination with the ingredients in Categories B or C, the maximum dose limit is 8%.
	2		X	◎	—	
B		Resorcinol	X	○	—	●Category B can only be used in combination with ingredients from Category A Group 2.
C		Other	X	○	1/2 ≦ ≦1	—

◎: Essential composing ingredient ○: Optional composing ingredient ×: Non-composing ingredient

C. Dosage form

I. Limited to creams, ointments, gels for external use, solutions for external use, lotions and liniments.

II. For the ingredients with dosage forms excluded in the ingredient table, they cannot be present as the excluded dosage forms.

D. Use (indication)

Treatment of acne vulgaris (acne, pimples)

E. Precautions

I. Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product.

(II) Children under the age of 2 years.

(Must be indicated for liniments containing Menthol or Camphor.)

II. Under the following conditions, consult your doctor before use:

(I) Where there is deep skin tissue infection.

(II) Children under the age of 12 years.

(III) Where there is sensitive skin.

(Must be indicated for preparations containing Benzoyl peroxide.)

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Pregnant women, women who might be pregnant, and breastfeeding women.

(II) You are currently using another topical drug for acne vulgaris (pimples, acne) or other topical acne products.

IV. Other

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III) Do not exceed the stated dose or number of uses.

(IV) When the area to be applied to or the surrounding area is dirty, clean first and then apply the drug.

(V) Wash hands thoroughly before and after using this drug.

(VI) This drug is for use on the area with acne vulgaris (acne, pimples) only, and can not be taken orally or used in the eyes, nor around the eyes or mucous membranes (such as the mouth, nose, vagina, scrotum or genital area).

(VII) Be careful not to get this drug in the eye. If contact occurs, rinse eyes immediately with water or warm water and see an ophthalmologist right away.

(VIII) Do not use this drug on damaged skin or a large body surface (an area as large as your two palms).

(IX) After application, keep the area applied to breathe. Do not cover it to avoid side effects.

(X) To check whether this drug will irritate your skin, test it on one or two small areas before use, do not use this drug if irritation occurs.

(XI) Avoid sun exposure and other skin irritants on treated areas. (Must be indicated for preparations containing Benzoyl peroxide.)

(XII) Avoid contact with hair and dyed fabrics, because this drug will result in color fading of hair and clothes.

(Must be indicated for preparations containing Benzoyl peroxide.)

F. Dosage and Administration

Adults and 12 years of age and over.	1. Wash and then dry your face. Apply a thin layer of the drug to the affected area. 2. Use it once a day at the beginning. Gradually increase the application frequency to 2-3 times a day when needed. 3. If there is dry skin or peeling, reduce the application frequency to once a day or once every two days.

Children under the age of 12 years.	Consult your doctor.

G. Warnings

I. After applying the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

(I) The following information must be indicated for preparations containing Benzoyl peroxide:

Body part	Side effects
Skin	Redness, burning, itching, swelling, dry skin, peeling, and tingling.

II. After applying the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Discomfort other than that mentioned above.

(II) After seven days of use on the same area, feeling the condition has not improved or has worsened.

(III) In the case of dry skin, peeling, tingling or burning, aforesaid irritation is not improved after reducing the number of uses or concentration.

Diaper rash and Antimiliaria drug products

A. Scope

This guideline applies to all external preparations used to relieve diaper rash, or to relieve and prevent symptoms caused by miliaria.

B. Active ingredients

I. Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the dose limit for each active ingredient in Categories A, B, C, D and E.

Table 1. Active ingredient and dose, combination rules, and combination coefficient

Category	Group	Active ingredient	Dose limit	Combination rules and combination coefficient	
A	1	Zinc oxide	1 – 50%	◎	When two ingredients of the same Category are used in combination, the combination coefficient cannot be greater than 1.
	2	Calamine	1 – 50%	◎	
B		d-Camphor	0.1 – 1%	○	Can be used in combination with at most one ingredient in the same Category.
		dl-Camphor	0.1 – 1%		
C	1	Vitamin A	250 – 2500 IU/g	○	
	2	Tocopherol acetate	0.05 – 0.5%	○	Can be used in combination with at most one ingredient in the same Group.
		Tocopherol	0.05 – 0.5%		
	3	Ergocalciferol	100 – 1000 IU/g	○	
	4	Panthenol	0.1 – 1%	○	
D		Crotamiton	0.5 – 5%	○	
E	1	Allantoin	0.2 – 2%	○	
	2	Ichthammol	0.15 – 1.5%	○	
	3	Glycyrrhetinic acid	0.05 – 0.5%	○	

◎: Essential composing ingredient ○: Optional composing ingredients

II. Combination rules (see Table 1):

(I) Essential composing ingredients: The active ingredients in category A of Table 1; the formula must contain at least one essential composing ingredient.

(II) Optional composing ingredients: The active ingredients in Categories B, C, D and E of Table 1, which can be used in combination with the active ingredients in Category A.

(III) The active ingredients in Category B and Category C Group 2 of Table 1 can be used in combination with at most one active ingredient in each Category (Group).

(IV) When the ingredients in Category B are used in combination, they can be the active ingredients (optional composing ingredients) or excipients. However, when they are used as active ingredients (optional composing ingredients), relevant technical information shall be attached in accordance with the stipulations of the Regulations for Registration of Medicinal Products.

III. Combination dose of active ingredients (see Table 1):

(I) The concentration of each active ingredient is as stipulated in Table 1.

(II) Ingredients from Table 1 Category A:

1. Dose limits for combination doses of active ingredients in Category A are as stipulated in Table 1.
2. When two active ingredients are combined, the combination coefficient cannot be greater than 1.
3. Combination coefficient = (X/mX)+(Y/mY)

X (or Y): The dose of composing ingredient X (or Y) in Category A.

mX (or mY): The maximum dose of the composing ingredient X (or Y) in Category A.

(III) When the preparation contains the ingredients in Categories B, C, D and E of Table 1, the combination dose of each active ingredient is the dose limit that stipulated in Table 1.

C. Dosage form

Limited to solutions for external use, liniments, lotions, ointments and creams.

D. Use (indication)

"To relieve diaper rash" or "to relieve or prevent symptoms caused by miliaria" (either description shall be indicated.)

E. Dosage and Administration

"Use when needed" or "one to four times a day" (either description shall be indicated.)	Apply an appropriate amount to the affected area.

F. Precautions

I. **Do not use in the following conditions:**

(I) People who are allergic to the ingredient(s) of this product.

(II) Children under the age of 2 years.

(Must be indicated for liniments containing Camphor.)

II. **Under the following conditions, consult your doctor before use:**

(I) Where there is deep skin tissue infection.

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Children, pregnant women, women who might be pregnant, and breastfeeding women.

(II) Children under the age of 2 years.

(Must be indicated for preparations (other than liniments) containing Camphor.)

IV. Other:

(I) Store properly to prevent children from accidentally taking this drug.

(II) Children use the medicine must under the guidance and supervision of a guardian.

(III) Avoid direct sunlight.

(IV) Do not exceed the stated dose or number of uses.

(V) When the area to be applied to or the surrounding area is dirty, clean first and then apply the medicine.

(VI) Wash hands thoroughly before and after using this drug.

(VII) This drug is for external use only and must not be taken orally or used in the eyes, nor around the eyes or mucous membranes (such as the mouth, nose, vagina, scrotum or genital area).

(VIII) Be careful not to get this drug in the eye. If contact occurs, rinse eyes immediately with water or warm water and see an ophthalmologist right away.

(IX) Do not use this drug on a large body surface (an area as large as your two palms).

(X) After application, keep the area applied to breathe. Do not cover it to avoid side effects.

(XI) The following shall be indicated on the external containers or external packages of flammable solutions for external use: Keep away from fire sources .

(XII) Use is not recommended where the affected area has the following conditions:

1. There are wounds, redness or swelling.
2. There is pus or ulceration in wounds.

G. Warnings

I. After applying the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

Body part	Side effects

Skin	Rash, redness, itching, irritation or peeling.

II. After applying the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Discomfort other than that mentioned above.

(II) After 7 days of continuous use, the symptoms have not improved or have worsened.

Dry skin and Exfoliation drug products

A. Scope

The guideline applies to all preparations for external use for dry-skin relieving, peeling and flaking caused by coldness or dryness, or for exfoliation.

B. Active ingredients

I. Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the dose limit for each active ingredient in Categories A, B, C, D and E.

Table 1. Active ingredient and dose, combination rules, and combination coefficient

Category	Group	Active ingredient	Dose limit	Combination rules and combination coefficient	
A	1	Urea	(Fixed dose) 10%	◎	1.Can be used in combination with at most one ingredient in the same Category. 2. Salicylic acid is for single-ingredient preparation only.
	2	Salicylic acid	1 – 2%	◎	
	3	Chlorhexidine hydrochloride (Chlorhexidine dihydrochloride)	0.1 – 0.2%	◎	
		Chlorhexidine gluconate (Chlorhexidine digluconate)	0.1 – 0.2%		
B		Zinc oxide	0.2 – 8%	○	
C	1	d-Camphor	0.1 – 1%	○	Can be used in combination with at most one ingredient in the same Group.
		dl-Camphor	0.1 – 1%		
	2	dl-Menthol	0.1 – 1%	○	Can be used in combination with at most one ingredient in the same Group.
		l-Menthol	0.1 – 1%		

D		Tocopherol acetate	0.05 – 2%	◯	Can be used in combination with at most one ingredient in the same Category.
		Tocopherol	0.05 – 2%		
E		Glycyrrhetinic acid	0.05 – 0.5%	◯	

◎: Essential composing ingredient ◯: Optional composing ingredient

II. Combination rules (see Table 1):

(I) Essential composing ingredients: The active ingredients from category A of Table 1. The formula must contain one and at most one essential composing ingredient.

(II) Optional composing ingredients: The active ingredients from Categories B, C, D and E of Table 1, which can be used in combination with the active ingredients in Category A.

(III) Salicylic acid in Table 1 Category A Group 2 is limited to single-ingredient preparation only.

(IV) The active ingredients in Category C Groups 1 ~ 2 and in Category D of Table 1 can be used in combination with at most one active ingredient in each Category (Group).

(V) When the ingredients in Category C are used in combination, they can be the active ingredients (optional composing ingredients) or excipients. However, when they are used as active ingredients (optional composing ingredients), relevant technical information shall be attached in accordance with the stipulations of the Regulations for Registration of Medicinal Products.

III. Combination dose of active ingredients (see Table 1):

(I) The concentration of each active ingredient is as stipulated in Table 1.

(II) The dose limit specified in Category A Group 1 of Table 1 is a fixed dose.

(III) The combination dose of each active ingredient in Category A Group 2, Group 3, and Categories B, C, D and E is the dose limit that stipulated in Table 1.

C. Dosage form

Limited to solutions for external use, liniments, lotions, ointments and creams only.

D. Use (indication)

I. The single-ingredient preparation that contain Urea or Salicylic acid: Exfoliation

II. Preparations other than the single-ingredient preparation that contain Urea or Salicylic acid: Relief of dry skin, peeling and flaking caused by coldness or dryness.

E. Precautions

I. Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product.

(II) Children under the age of 2 years.

(Must be indicated for liniments containing Menthol or Camphor.)

II. Under the following conditions, consult your doctor before use:

(I) Where there is deep skin tissue infection.

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Children, pregnant women, women who might be pregnant, and breastfeeding women.

(II) People who are undergoing treatment by a doctor.

(Must be indicated for preparations containing Urea.)

(III) Children under the age of 2 years. (Must be indicated for preparations (other than liniments) containing Menthol or Camphor.)

IV. Other

(I) Store properly to prevent children from accidentally taking this drug.

(II) Children use the medicine must under the guidance and supervision of a guardian.

(III) Avoid direct sunlight.

(IV) Do not exceed the recommended dose or number of uses.

(V) When the area or the surrounding area to be applied to is dirty, clean first and then apply the medicine.

(VI) Wash hands thoroughly before and after using this drug.

(VII) This drug is for external use only and should not be taken orally or used in the eyes, nor around the eyes or mucous membranes (such as the mouth, nose, vagina, scrotum or genital area).

(VIII) Be careful not to get the drug in the eye. If contact occurs, rinse eyes immediately with water or warm water and see an ophthalmologist right away.

(IX) Do not use this drug on a large area of your body surface (an area as large as your two palms).

(X) After application, keep the area applied to breathe. Do not cover it to avoid side effects.

(XI) The following warning must be indicated on the external containers or external packages of flammable solutions for external use: Keep away from fire.

(XII) This drug is not a cosmetic and must not be used as facial foundation makeup.

(Must be indicated for preparations containing Urea.)

(XIII) Large-scale and long-term use will cause Salicylic acid reaction (tinnitus, dizziness, nausea, vomiting, etc.).
(Must be indicated for preparations containing Salicylic acid.)

(XIV) Avoid contact with clothing, plastic, wood and metal. (Must be indicated for preparations containing Salicylic acid.)

(XV) Use is not recommended where the affected area has the following conditions:

1. There are wounds, redness or swelling.
2. There is pus or ulceration in wounds.
3. There are wounds with scabbing or peeling scabs. (Must be indicated for preparations containing Urea.)

F. Dosage and Administration

I. The single-ingredient preparation that contain Urea or Salicylic acid:

Once to twice a day	Apply an appropriate amount to the affected area.

II. Preparations other than the single-ingredient preparation that contain Urea or Salicylic acid:

"Use when needed" or "one to four times a day" (either description shall be indicated.)	Apply an appropriate amount to the affected area.

G. Warnings

I. After applying the medicine, if any of the following side effects occur, stop using it immediately, and bring this package insert to consult your doctor, pharmacist or assistant pharmacist.

(I)

Body part	Side effects
Skin	Rash, redness, itching and irritation.

(II) The following information must be indicated for preparations containing Salicylic acid:

Body part	Side effects
Skin	Erythema, itching and tingling
Other	Salicylic acid reaction (tinnitus, dizziness, nausea, vomiting, etc.).

II. After applying the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Discomfort other than that mentioned above.

(II) After 7 days of continuous use, the symptoms have not improved or have worsened.

Topical preparations -- others

A. Scope

This guideline applies to preparations for external use containing Phenothrin, Capsaicin, Hydroquinone, Selenium sulfide, Pyrithione zinc and Salicylic acid (17%).

B. Active ingredients

I. Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the maximum dose for each active ingredient.

Table 1. Active ingredient and dose

Category	Group	Active ingredient	maximum dose	Use (indication)	Dosage and Administration
Anti-pediculosis agent	A	Phenothrin	0.2% w/w	Treatment of head lice and pubic lice	Apply to hair of the affected part while hair is dry; dry naturally for two hours; then wash off. Use a fine-toothed comb to remove the lice eggs. Use the agent again after seven to nine days if necessary.
Other	B	Capsaicin	0.025%	Temporary relief of local pain	Do not use more than four times a day.
		Hydroquinone	1%	Reduction of dark spots, freckles or other pigmentation	Apply once in the morning and once in the evening.
		Selenium sulfide (= Selenium disulfide)	1%	Dandruff	General use: In the first two weeks, apply to the affected area twice a week, and then once a week or once every two weeks.

		Pyrithione zinc	2%	Dandruff	General use: In the first two weeks, apply to the affected area twice a week, and then once a week or once every two weeks.
		Salicylic acid	17%	Wart treatment	Once a day, apply to the affected area

II. Combination rules

The drugs governed by this guideline are limited to single-ingredient preparations only.

C. Dosage form

Limited to creams, ointments, gels for external use, lotions, solutions for external use, patches, and powders for external use.

D. Use (indication)

Indicate the "use (indications)" of the active ingredient in accordance with Table 1.

E. Precautions

I. Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product.

(II) When the scalp is scraped or inflamed. (Must be indicated for preparations containing Selenium sulfide or Pyrithione zinc.)

II. Under the following conditions, consult your doctor before use:

(I) Where there is deep skin tissue infection.

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) Children, pregnant women, women who might be pregnant, and breastfeeding women.

IV. Other:

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III)Do not exceed the stated dose or number of uses.

(IV) When the area to be applied to or the surrounding area is dirty, clean first and then apply the drug.

(V) Wash hands thoroughly before and after using this drug.

(VII) This drug is for external use only and may not be taken orally, nor used around the eyes or mucous membranes (such as the mouth, nose, vagina, scrotum or genital area).

(VII) Be careful not to get this drug in the eye. If contact occurs, rinse eyes immediately with water or warm water and see an ophthalmologist right away.

(VIII) Do not use this drug on a large body surface (an area as large as your two palms).

(Must be indicated for preparations containing Capsaicin or Hydroquinone.)

(IX) After application, keep the area applied to breathe. Do not cover it to avoid side effects.

(X) May damage jewelry. Remove jewelry before using this drug, and thoroughly wash the affected area after treatment. (Must be indicated for preparations containing Selenium sulfide.)

(XI) Should not be used for long-term. Long-term use will result in hair loss.

(Must be indicated for preparations containing Selenium sulfide.)

(XII) Large-scale and long-term use will cause Salicylic acid reaction (tinnitus, dizziness, nausea, vomiting, etc.).

(Must be indicated for preparations containing Salicylic acid.)

(XIII) Avoid contact with clothing, plastic, wood and metal. (Must be indicated for preparations containing Salicylic acid.)

F. Dosage and Administration

Indicate the "Dosage and Administration" of the active ingredient in accordance with Table 1.

G. Warnings

I. After applying the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

(I) The following information must be indicated for preparations containing Phenothrin:

Body part	Side effects
Skin	Allergic reactions.

(II) The following information must be indicated for preparations containing Selenium sulfide:

Body part	Side effects
Skin	Local irritation
Head	Hair loss and faded hair color. Oily or dry hair and scalp.

(III) The following information must be indicated for preparations containing Pyrithione zinc:

Body part	Side effects
Skin	Contact dermatitis

(IV) The following information must be indicated for preparations containing Capsaicin:

Body part	Side effects
Skin	Skin burning, tingling and erythema.
Other	Pungent sensation and irritating cough.

(V) The following information must be indicated for preparations containing Hydroquinone:

Body part	Side effects
Skin	Local erythema, tingling and allergic dermatitis.

(VI) The following information must be indicated for preparations containing Salicylic acid:

Body part	Side effects
Skin	Erythema, itching and tingling.
Other	Salicylic acid reaction (tinnitus, dizziness, nausea, vomiting, etc.).

II. After applyling the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Discomfort other than that mentioned above.

(II) Feel the condition has not improved or become worsened.

Topical Hemorrhoid drug products

A. Scope

This guideline applies to preparations intended to relieve symptoms caused by hemorrhoids, that are used for the external of perianal area or internal of the lower rectal area .

B. Active ingredients

I. Active ingredient and dose:

(I) The active ingredients specified in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the dose limit or single dose limit for each active ingredient in each category.

Table 1. Active ingredient and dose

Category	Group	Active ingredient	Group I [*1]	Group II [*2]	Group III [*3]
			Dose limit (%) [*4]	Single dose limit (mg) [*4]	Dose limit (%) [*4]
A Local anesthesia		Dibucaine	0.25-0.5	5-10	0.25-1
		Dibucaine hydrochloride	0.25-0.5	5-10	0.25-1
		Procaine hydrochloride	1-2	20-40	—
		Lidocaine	1.5-3	30-60	2-5
		Lidocaine hydrochloride	1.5-3	30-60	—
		Dyclonine hydrochloride	—	—	0.5-1
		Pramoxine hydrochloride	—	—	1 (Fixed dose)
		Tetracaine	—	—	0.5-1
		Tetracaine hydrochloride	—	—	0.5-1
B Vasoconstriction		Ephedrine hydrochloride	0.2-1	4-20	—
		Tetrahydrozoline hydrochloride	0.01-0.05	0.2-1	—
		Naphazoline hydrochloride	0.01-0.05	0.2-1	—
		Phenylephrine hydrochloride	0.05-0.25	1-5	0.25 (Fixed dose)
		dl-Methylephedrine hydrochloride	0.1-0.5	2-10	—

Category	Group	Active ingredient	Group I [*1]	Group II [*2]	Group III [*3]
			Dose limit (%) [*4]	Single dose limit (mg) [*4]	Dose limit (%) [*4]
C Steroids		Hydrocortisone	0.1-0.5	1-5	—
		Hydrocortisone acetate	0.1-0.5	1-5	—
		Prednisolone	0.02-0.1	0.2-1	—
		Prednisolone acetate	0.02-0.1	0.2-1	—
D Astringent		Zinc oxide	4-20	80-400	5-25
		Calamine (based on the zinc oxide content of calamine)	—	—	5-25
E Disinfection		Isopropylmethylphenol	0.02-0.1	0.4-2	—
		Cetylpyridinium chloride	0.04-0.2	0.8-4	—
		Benzalkonium chloride	0.02-0.1	0.4-2	—
		Chlorhexidine hydrochloride	0.1-0.5	2-10	—
		Chlorhexidine gluconate	0.2-1	—	—
		Cetrimide	0.025-0.125	0.5-2.5	—
		Resorcin (Resorcinol)	0.4-2	8-40	1-3
F	1 Antihistamines	Diphenylpyraline hydrochloride	0.02-0.1	0.4-2	—
		Diphenhydramine	0.2-1	4-20	—
		Diphenhydramine hydrochloride	0.2-1	4-20	—
		Chlorpheniramine maleate	0.04-0.2	0.8-4	—
	2	Crotamiton	1-5	20-100	—
G	1 Anti-inflammatory	Allantoin	0.2-1	4-20	—
		Aluminum chlorhydroxy allantoinate (Alcloxa)	0.2-1	4-20	0.2-2
		Ichthammol	2-10	40-200	—
		Glycyrrhetinic acid	0.3-1.5	6-30	—
		1,4-Dimethyl-7-isopropylazulene (Guaiazulene)	0.008-0.04	0.16-0.8	—
		Purified yolk lecithin	1-5	20-100	—
			Extracts (amount converted from original crude drug ingredient)		
G	2 Crude drug ingredient	Rosskastanien seeds (Horse Chestnut Seed, *Aesculus hippocastanum* Seed)	2.5-25	50-500	—
H Vitamin E		Tocopherol acetate	0.6-3	12-60	—
I Other	1	*d*-Camphor	0.1-1	2-20	0.1-3
		dl-Camphor	0.1-1	2-20	0.1-3
	2	Mentha oil	0.075-0.75	1.5-15	—
		l-Menthol	0.05-0.5	1-10	0.1-1
		dl-Menthol	0.05-0.5	1-10	0.1-1
	3	Eucalyptus oil	0.05-0.5	1-10	0.1-1

*1. Group I preparation: Applied to the external of anus or intrarectal use.

*2. Group II preparation: Applied to suppositories or preparations as a single dose in prefilled disposable applicators.

*3. Group III preparation: Applied to the external of anus or intrarectal use.

*4. If the dose for each active ingredient in Table 1 are not stipulated for Groups I, II, or III, the preparations in those groups may not be used in combination with that ingredient.

II. Combination rules:

(I) Groups I and II:

1. Essential composing ingredients: The active ingredients in Category A of Table 1. The formula must contain one and at most one essential composing ingredient.
2. Optional composing ingredients: The active ingredients from Categories B, C, D, E, F, G, H, and I of Table 1, which can be used in combination with the essential composing ingredients in Category A.
3. The active ingredients in Categories B, C, E, F, and H of Table 1 can be used in combination with at most one active ingredient in each category.
4. The active ingredients in Category I of Table 1 can be used in combination with at most one active ingredient in each group.
5. There are no restrictions over the combination of active ingredients in Categories D and G of Table 1, but Allantoin and Aluminum chlorhydroxy allantoinate (Alcloxa) in Category G Group 1 cannot be used in combination together.
6. The extract of Rosskastanien seeds (horse chestnut seed, *Aesculus hippocastanum* seed) in Category G Group 2 of Table 1 should be water base extracts; it can be extracted with water or with diluted ethanol below 30% , can't be used as a powder in combination.

7. Qualitative tests shall be carried out for Rosskastanien seeds (horse chestnut seed, *Aesculus hippocastanum* seed) in Category G Group 2 of Table 1, and quantitative tests shall be carried out for crude drug ingredients with indicator ingredients as recorded in the pharmacopoeias.
8. When the ingredients in Category I of Table 1 are used in combination, they can be the active ingredients (optional composing ingredients) or excipients. However, when they are used as active ingredients (optional composing ingredients), applicable requirements for active ingredients stipulated in the Regulations for Registration of Medicinal Products shall be followed.

(II) Group III:

1. For the active ingredients in Categories A, B, and D of Table 1, one ingredient from each of Category can be used in combination with each other (e.g. A+B, A+D, B+D, and A+B+D).
2. For the active ingredients in Categories A and D of Table 1, one ingredient from each of Category can be used in combination with Resorcin (Resorcinol) in Category E or Aluminum chlorhydroxy allantoinate (Alcloxa) in Category G (e.g. A+E or G, D+E or G, A+D+E or G).
3. For the active ingredients in Categories I and D of Table 1, one ingredient from each Category can be used in combination with each other and be used in combination with Resorcin (Resorcinol) in Category E or Aluminum chlorhydroxy allantoinate (Alcloxa) in Category G (e.g. I+D, I+E or G, I+D+E or G).

4. For the active ingredients in Categories B, D, and I of Table 1, one active ingredient from each of Category can be used in combination with each other (e.g. B+D+I).

III. Combination dose of active ingredients:

(I) Groups I and II:

1. For the Group I preparations, the content of each active ingredient may not exceed the dose limit specified in Table 1.
2. For the Group II preparations, the combination amount of each active ingredient may not exceed the single dose limit specified in Table 1.
3. For preparations to be applied externally and used-as a single dose in prefilled disposable applicators, the combination amount of each active ingredient shall follow the dose limit for Group I and single dose limit for Group II at the same time.

(II) Group III:

1. The active ingredients of the formula in Group III preparations may not exceed the dose limit specified in Table 1.
2. The combination amount for Pramoxine hydrochloride in Category A of Table 1 and Phenylephrine hydrochloride in Category B of Table 1 are fixed dose.

(III) Calculation of the content of each active ingredient in Table 1:
The concentration of suppositories, creams, and ointments shall be expressed in W/W %.

C. Dosage form

Limited to suppositories, ointments, and creams .

D. Use (indications)

To relieve symptoms caused by hemorrhoids (pain, burning, itching, swelling, hemorrhoid bleeding, ulcers) *1 and to prevent local infections *2.

I. The symptoms in parentheses of *1 and the descriptions of *2 shall be indicated according to the ingredients (see the right column of Use (indications) in Table 2). If the ingredients are not contained, the symptoms cannot be indicated. Meanwhile, preparations containing the active ingredients indicated in each category of Table 1 can only be indicated when their combination amount reaching the 1/2 (inclusive) of the maximum dose or the maximum single dose that specified in Table 1.

Table 2. Use (indications)

Category	Symptoms of use (indications)
A	Pain, burning, itching
B	Swelling, hemorrhoid bleeding
C	Itching, swelling, hemorrhoid bleeding
D	Burning, swelling, hemorrhoid bleeding, ulcers
E	Prevent local infections
F	Itching
I	Pain, burning

II. The ingredients in Category I may be described "Provide a cooling sensitive"

E. Precautions

I. Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product.

(II) People with purulent wounds.

(Must be indicated for preparations containing steroids in Category C.)

(III) Breastfeeding women

(Must be indicated for suppositories or preparations for intrarectal use containing diphenhydramine or diphenhydramine hydrochloride)

II. Under the following conditions, consult your doctor before use:

(I) Children under the age of 12 years.

(II) People who have edema symptoms or have a history of the following diseases: Kidney disease, high blood pressure, and heart disease.

(Must be indicated for suppositories or preparations for intrarectal use containing glycyrrhetinic acid [if the maximum daily dose is 40 mg and above].)

(III) People who have difficulty urination or a history of glaucoma.

(Must be indicated for suppositories or preparations for intrarectal use containing phenylephrine hydrochloride or the ingredients in Category F Group 1 [antihistamines ingredients].)

(IV) People who are taking antidepressant or have a history of the following diseases: high blood pressure, heart disease, diabetes, hyperthyroidism, or difficulty in urination due to prostatic hyperplasia.

(Must be indicated for suppositories or preparations for intrarectal use containing the ingredients in Category B [vasoconstrictive ingredients])

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) People who are undergoing hemorrhoids treatment by a doctor.

(II) Pregnant women, women who might be pregnant, and breastfeeding women.
(However, if "I. Do not use in the following conditions" is indicated, breastfeeding women shall be omitted)

(III) Adults aged 65 years and over.
(Must be indicated for suppositories or preparations for intrarectal use containing *dl*-methylephedrine hydrochloride or glycyrrhizic acid [if the maximum daily dose is 40 mg and above].)

(IV) People who are taking medicines containing antihistamines ingredients to common cold, antitussive or expectorant, rhinitis, motion sickness, or anti-allergic.
(Must be indicated for suppositories or preparations for intrarectal use containing the ingredients in Category F Group 1 [antihistamines ingredients].)

(V) Continuous use is required after having used this drug for seven days.

IV.Other:

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III) Do not exceed the stated dose.

(IV) Clean the affected area with a neutral soap and warm water and gently pat the area dry with tissues or a soft towel before application of this product.

(V) Be careful not to get the medicine in the eye. If contact occurs, rinse eyes immediately with water or warm water and see an ophthalmologist right away.

(VI) This drug is for the external of perianal area or internal of the lower rectal area only and can not be taken orally.

(VII) The drug may cause drowsiness, so do not drive or operate dangerous machinery.

(Must be indicated for suppositories or preparations for intrarectal use containing the ingredients in Category F Gruop 1 [antihistamines ingredients].)

(VIII) Do not use on areas that are bleeding or have wounds.

(Must be indicated for preparations containing resorcin [resorcinol].)

(IX) The following shall be indicated on the external containers or external packages of suppositories: Do not freeze this drug.

F. Dosage and Administration

I. Ointments and creams:

Adults and 12 years of age and over.	Apply an appropriate amount to the areas of the anus. Do not use more than three times a day.
Children under the age of 12 years.	Consult your doctor.

II. Suppositories:

Adults and 12 years of age and over.	Use one dose each time. Insert it through the anus. Do not use more than three times a day. The drug cannot be halved.

Children under the age of 12 years.	Consult your doctor.

III. Preparation for single dose in prefilled disposable applicators:

Adults and 12 years of age and over.	Use one dose each time. Insert the whole amount through the anus. Do not use more than three times a day.
Children under the age of 12 years.	Consult your doctor.

IV. Preparations not as a single dose for intrarectal use:

Adults and 12 years of age and over.	Manufacturers shall specify the usage of syringes according to the product design.
Children under the age of 12 years.	Consult your doctor.

G. Warnings

I. After applying the medicine, if any of the following side effects occur, stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

Body part	Side effects
Skin	Rash, redness, itching, swelling, dryness, hot sensation, tingling, inflammation [1)], and pain [1)]
Urinary organs	difficulty in urination [2)]
Other	Irritation, dry mouth [2)], drowsiness [2)], purulence [3)]

[1)] Must be indicated for preparations containing the ingredients in Category A (local anesthetic ingredients), menthol (as active ingredients), or resorcin (resorcinol).

[2] Must be indicated for suppositories or preparations for intrarectal use containing the ingredients in Category F Group 1 (antihistamines ingredients).

[3] Must be indicated for preparations containing the ingredients in Category C (steroids ingredients).

II. After applying the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Persistent bleeding.

(II) Discomfort other than that mentioned above.

(III) After seven days of use, feeling the condition has not improved or has worsened.

(IV) Shock (allergic reaction), skin pruritus, hoarseness of voice, sneezing, itchy throat, difficulty breathing, palpitations or unconsciousness after use.
(Must be indicated for suppositories or preparations for intrarectal use containing dibucaine, dibucaine hydrochloride, lidocaine hydrochloride, or lidocaine.)

(V) Fatigued of the hands and feet, numbness, tight, stiff, weakness, muscular ache, unknown bruising, nosebleeds, bleeding gums, pale appearance, fatigue, palpitations, asthma, dizziness, hematuria, fever, or chilling.

Nasal drug products

A. Scope

This guideline applies to nasal preparations for the temporary relief of symptoms including stuffy nose, runny nose, or sneezing, caused by rhinitis, allergic rhinitis, allergies, or cold.

B. Active ingredient

I. Active ingredients and dose:

(I) The active ingredients stipulated in Table 1 are applicable to this guideline.

(II) Table 1 stipulates the maximum dose or fixed dose for each active ingredient in category A, B, C, and D.

Table 1. Active ingredients and dose

Category	Group	Active ingredient	Maximum dose (%)
A Nasal decongestant	1	Oxymetazoline hydrochloride	(Fixed dose) 0.025% and 0.05%
		Xylometazoline hydrochloride	(Fixed dose) 0.05% and 0.1%
	2	Ephedrine hydrochloride	0.5%
		Naphazoline hydrochloride	0.05%
		Naphazoline nitrate	0.05%
		Phenylephrine hydrochloride	(Fixed dose) 1%
			0.5%

Category	Active ingredient	Maximum dose (%)
B Antihistamine	Diphenhydramine hydrochloride	0.2%
	Chlorpheniramine maleate	0.5%
C Local anesthesia	Lidocaine	0.5%
D Anti-inflammation	Dipotassium glycyrrhizinate	0.3%

II. Combination rules (see Table 2):

(I) Essential composing ingredients: The active ingredients in Category A Group1 and Group 2 of Table 1.The formula must contain at least one essential composing ingredient.

(II) Oxymetazoline hydrochloride and xylometazoline hydrochloride in Group 1 and phenylephrine hydrochloride 1% in Category A Group 2 of Table 1 are limited to single-ingredient preparations only.

(III) Optional composing ingredients: The active ingredients in Categories B, C, and D of Table 1, which can be used in combination with essential combosing ingredients in Category A Group 2.

(IV) The active ingredients in Category A Group 2 and Category B of Table 1 can be used in combination with at most one active ingredient in each Category (Group).

III. Combination dose of active ingredients (see Table 2):

(I) The combination dose of each active ingredient in Category A Group 1of Table 1 is a fixed dose.

(II) Products that use ingredients in Category A Group 2 of Table 1 as the main ingredient:

1. Ingredients in Category A Group 2 of Table 1:

(1) The combination coefficient of the composing ingredients in Category A Group 2 must be between 1 and 1/2.

(2) Combination coefficient ＝X / mX

X: The dose of the composing ingredient X in Category A Group 2

mX: The maximum dose of the composing ingredient X in Category A Group 2

2. The dose of Phenylephrine hydrochloride 1% in Category A Group 2 of Table 1 is a fixed dose.

3. When the formula contains an ingredient in Category B, C or D of Table 1:

(1) The combination coefficient of the ingredients in that Category must be between 1 and 1/5.

(2) Combination coefficient ＝X / mX

X: The dose of the composing ingredient X in Category B (Category C or Category D)

mX: The maximum dose of the composing ingredient X in Category B (Category C or Category D)

4. For preparations to be used in children 3 to less than 6 years of age, the maximum dose for the active ingredient of the preparations must be 1/2 of the maximum dose stipulated in Table 1.

(III) The combination dose in Table 1 must be calculated in w/v %.

C. Dosage form

Nasal drop, nasal solution, nasal spray, nasal aerosols, nasal spray suspension.

D. Use (indication)

To temporarily relieve symptoms caused by rhinitis, allergic rhinitis, allergies, or a cold, (including stuffy nose, runny nose, sneezing※).

※ Descriptions of the symptoms in parentheses vary according to the ingredients (see Table 3). If the ingredients are not used, the symptoms cannot be indicated.

Table 3.

Category	Symptoms of use (indication)
A	stuffy nose, Runny nose
B	Sneezing

E. Precautions

I. Do not use in the following conditions:

(I) People who are allergic to the ingredient(s) of this product.

(II) Breastfeeding women
(Must be indicated for preparations containing diphenhydramine hydrochloride in Category B.)

II. Under the following conditions, consult your doctor before use:

(I) Children under the age of 3 years (or 6 years).
(Please indicate in accordance with the requirements of the usage and dosage.)

(II) Children under the age of 12 years.
(Must be indicated for preparations containing naphazoline hydrochloride 0.05% or naphazoline nitrate 0.05% in Category A Group 2.)

(III) People who have heart disease, hypertension, thyroid disease, diabetes, glaucoma, or difficulty in urination due to prostatic hyoerplasia.

(IV) While taking MAOIs or within two weeks after discontinuation of MAOIs. If you do not know whether the drugs you are taking contain MAOI, please consult your doctor or pharmacist.

(Must be indicated for preparations containing phenylephrine hydrochloride in Category A Group 2.)

III. Under the following conditions, consult your doctor, pharmacist or assistant pharmacist before use:

(I) People who are undergoing treatment by a doctor.

(II) Pregnant women, women who might be pregnant, and breastfeeding women.

(However, if "1. Do not use in the following situations" is indicated, breastfeeding women shall be omitted.)

(III) People who are taking medicines containing decongestants such as general cold, rhinitis, or allergies.

IV. Other

(I) Store properly to prevent children from accidentally taking this drug.

(II) Avoid direct sunlight.

(III) Do not exceed the stated dose.

(IV) Do not use this medicine for more than seven days, even symptoms have improved after using. Frequent or prolonged use may cause stuffy nose to recur or worsen.

(V) To avoid spread infection, do not share this product with others.

(VI) May cause temporary discomfort such as dryness, burning, stinging, sneezing or an increase in nasal discharge after use.

(VII) Blow the nose prior to use.

F. Dosage and Administration

I. Preparations that use ingredient in Category A Group 1 as the main ingredient:

(I) Dosage and Administration of preparations containing oxymetazoline 0.05%

6 years of age and over.	Apply ◯(~◯) sprays (or drops) in each nostril, not more often than every 10-12 hours. * The maximum of ◯ can not exceed 3.
Children under the age of 6 years.	Consult your doctor.

(II) Dosage and Administration of preparations containing oxymetazoline 0.025%

Children 3 to less than 6 years of age.	Apply ◯(~◯) sprays (or drops) in each nostril, not more often than every 10-12 hours. * The maximum of ◯ can not exceed 3.
Children under the age of 3 years.	Consult your doctor.

(III) Dosage and Administration of preparations containing xylometazoline 0.1%

12 years of age and over.	Apply ◯(~◯) sprays (or drops) in each nostril, not more often than every 8-10 hours. * The maximum of ◯ can not exceed 3.
Children under the age of 12 years.	Consult your doctor.

(IV) Dosage and Administration of preparations containing xylometazoline 0.05%

Children 3 to less than 12 years of age	Apply ◯(~◯) sprays (or drops) in each nostril, not more often than every 8-10 hours.

	* The maximum of ◯ can not exceed 3.
Children under the age of 3 years.	Consult your doctor.

II. Preparations that use ingredient in Category A Group 2 as the main ingredient:

(I) Usage and dosage of preparations other than single-ingredient ones containing phenylephrine hydrochloride 1% and preparations containing naphazoline hydrochloride / naphazoline nitrate 0.05%:

6 years of age and over.	Apply ◯(~◯) sprays (or drops) in each nostril, not more often than every 4 hours. * The maximum of ◯ can not exceed 3.
Children 3 to less than 6 years of age.	Apply ◯(~◯) sprays (or drops) in each nostril, not more often than every 4 hours. * The maximum of ◯ can not exceed 3.
Children under the age of 3 years.	Consult your doctor.

(II) Usage and dosage of single-ingredient preparations containing phenylephrine hydrochloride1%:

12 years of age and over.	Apply ◯(~◯) sprays (or drops) in each nostril, not more often than every 4 hours. * The maximum of ◯ can not exceed 3.
Children under the age of 12 years.	Consult your doctor.

(III) Usage and dosage of preparations containing naphazoline hydrochloride / naphazoline nitrate 0.05% (including single-ingredient and combination preparations):

12 years of age and over.	Apply ◯(~◯) sprays (or drops) in each nostril, not more often than every 4 hours. * The maximum of ◯ can not exceed 3.

Children under the age of 12 years.	Consult your doctor.

III. Usage and dosage of the preparations include the 「children aged 3 to less than 6 years of age」 must use the metered dose spray containers.

G. Warnings

I. After useing the medicine, if any of the following side effects occured, please stop using it immediately, and take this package insert to consult your doctor, pharmacist or assistant pharmacist.

Body part	Side effects
Skin	Rash, redness, and itchiness
Nasal cavity	Swelling and irritation

II. After useing the medicine, if any of the following symptoms occur, stop using it immediately, and seek medical advice:

(I) Discomfort other than that mentioned above.

(II) Shock (allergic reactions): Symptoms occurred right after use such as skin itchiness, urticaria, hoarseness, sneezing, throat itchiness, difficulty breathing, palpitations, or unconsciousness.
(Must be indicated for preparations containing lidocaine in Category C.)

(III) Persistent nasal congestion, or after 3 days of continuous use, the symptoms have not improved or have worsened.

Table 2: Combination rules and combination coefficient

Category	Group	Active ingredient	Combination rules	Combination coefficient	Notes
A Nasal decongestant	1	Oxymetazoline hydrochloride	◎	Base on Table 1	For single-ingredient preparations only
		Xylometazoline hydrochloride	◎	Base on Table 1	For single-ingredient preparations only
	2	Ephedrine hydrochloride	◎	1/2≦ ≦1	● Can be combined with at most one ingredient from the same group. ● Phenylephrine hydrochloride 1% is a Fixed dose. ● Phenylephrine hydrochloride 1% is a single-ingredient preparation only.
		Naphazoline hydrochloride	◎	1/2≦ ≦1	
		Naphazoline nitrate	◎	1/2≦ ≦1	
		Phenylephrine hydrochloride	◎	1/2≦ ≦1	
B Antihistamine		Diphenhydramine hydrochloride	○	1/5≦ ≦1	Can be combined with at most one ingredient from the same category.
		Chlorpheniramine maleate	○	1/5≦ ≦1	
C Local anesthesia		Lidocaine	○	1/5≦ ≦1	
D Anti-inflammation		Dipotassium glycyrrhizinate	○	1/5≦ ≦1	

◎: Essential composing ingredient ○: Optional composing ingredients