醫療器材仿單標籤粘貼表

產品中文名稱 百膚可凝膠 申請廠商 昱浩藥品有限公司



- ※ 裝訂原廠之仿單、使用說明書及其中文仿單稿、最小包裝、標籤
- ※ 中文仿單稿包括適應症、禁忌症、型號(規格)、產品說明及注意事項等敘述,最後段須加刊製造廠名稱、地址及藥商名稱、地址,如有附件、配件請一併列明
- ※ 仿單標籤等實物過大或印於玻璃金屬容器等不便於黏貼時可將照相影本代替黏貼報核

醫療器材仿單標籤粘貼表

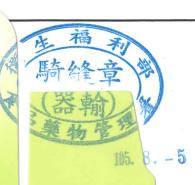
產品中文名稱

百膚可凝膠

申請廠商

昱浩藥品有限公司





BIONECT®

Hyaluronic acid sodium salt 0.2% Gel

Bionect Gel is hyaluronic acid sodium salt 0.2% gel.
While infiltrating into the basal layer and corium of skin,
it will enhance the proliferation and regeneration of the cell.
That provides an excellent repair ability to overcome the internal
and external cell damage factors.

With its incomparable small molecule, Bionect Gel can easily and rapidly permeate the skin layer to increase corium thickness and decrease epidermis thickness In addition, with this unique formula, it is able not only to retain moisture and elasticity of skin but also to nourish and revitalize dull skin in the purpose of reducing the appearance of fine lines.

Bionect* Gel is suitable for all skin types.

Composition:

Per 100g of gel contains hyaluronic acid sodium salt 200mg

Excipients:

Sobitol liquid, non-cristalisable, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, sodium dehydroacetate, carbomer 980, sodium hydroxide, purified water.

Fidia Farmaceutici S.p.A. Via Ponte della Fabbrica 3/A-35031 Abano Terme (PD) Italy

百膚可凝膠

衛署醫器輸字第016725號製造批號及保存期限。

Fidia Farmaceutici S.p.A.: Via Ponte della Fabbrica 3/A-35031 Abano Terme (PD), Italy

昱浩藥品有限公司:台北市信義區基隆 路二段109號5樓

BIONECT

Hyaluronic acid sodium salt 0.2% Gel

BIONECT®

0.2% Gel 30g

Active ingredient: Hyaluronic acid sodium salt 2mg/g (60mg per tube of 30g)

Description:

Bionect[®] can

- easily penetrate stratum corneum to capture water in and keep skin moisturizing.
- Increase thickness of corium (ECM protein formed)
- improve skin elastosis and also maintain its pH value.

To use

Use in the morning and evening.

Apply small amount of Bionect Gel to your face and neck after thoroughly clean and dry your skin.

fidia

Fidia Farmaceutici S.p.A.

Italy

※ 中文仿單稿包括適應症、禁 製造廠名稱、地址及藥商名稱

※ 仿單標籤等實物過大或印於玻

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百膚可凝膠

Bionect Gel

衛署醫器輸字第 016725 號

注意 使用前請務必詳閱原廠之使用說明書並遵照指示使用

組成:2mg/g

主成份:玻尿酸納鹽 (每管 30g 含有 60mg 玻尿酸鈉鹽)

<u>賦形劑</u>:山梨醇、對苯甲酸甲酯、對羟苯甲酸正丙酯、無水醋酸納高分子膠 980、氫氧化鈉及純水

用途:本產品為一種保護性的敷料,有助於創傷及皮膚傷口 (如擦傷,脫皮,輕度燙傷,淺層傷口,輕度曬傷)之癒合。亦可應用於紓解皮膚放射治療後之乾燥及褥瘡護理。

<u>使用方法</u>:使用本產品前,若有傷口,請先將傷口清潔、消毒,再將凝膠均勻塗抹於患部,一天 2-3 次。

注意事項:在使用前請先清潔及消毒欲塗抹本產品的區域。

警語:如果有過敏反應發生,請停止使用本品,儘快與您的醫生聯絡。孕婦及哺乳的婦女可使 用本品。使用百膚可不會影響到開車或操作機械的能力。請將本品放在兒童不易取得之處,本 產品僅限外用,若有誤食現象,請儘速就醫。一旦超過有效期限(印於外包裝上),請勿再使用 本產品。如無醫囑,請勿超過建議之使用量。

不良反應:對主成分玻尿酸或化學結構類似物,及本品之賦形劑過敏者,不可使用本產品。截至目前為止無使用本產品過量而導致中毒或全身性症狀之報告,極少數個案,曾有因使用而導致局部反應,但這些反應通常是輕微而且可自動獲得舒緩,請務必遵照仿單之指示使用,以減少不良反應發生的機會,若有不良反應發生,請立即請教你的醫師。

交互作用: 截至目前為主, 無本產品與抗生素或其他局部製劑有交互作用的報告被提出。

過量反應:截至目前為止,無過量使用本產品導致中毒反應的報告被提出。

有效期限及保存期限:有效期限標示於外盒包裝上,於室溫下儲存可保存3年。

規格: 0.2% 凝膠, 每管 30g。

製造廠:

Fidia Farmaceutici S.p.A.

Via Ponte della Fabbrica 3/A Abano Terme (PD) ITALY

藥商:

昱浩藥品有限公司

台北市信義區基隆路二段 109 號 5 樓







armaceutici 35031 Abano Terme (PD)

Materiale di proprietà della Fidia Farmaceutici S.p.A. che non deve essere assolutamente modificato o danneggiato. Da restituire al più presto

Istr. BIONECT Gel Taiwan

Data allestimento: Novembre 2006

Riferimento dis. tecnico: 147

Dimensioni: 139 x 180 mm

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Bionect® 0.2% Gel 30 g

Bionect® 0.2% Gel

Active ingredient: Hyaluronic acid sodium salt 2mg/g (60mg per tube of 30g) Excipients: sorbitol solution 70%, methyl p-hydroxybenzoate, propyl p-hydroxy-benzoate, sodium dehydroacetate, carbomer 980, sodium hydroxide, purified water.

Presentation Gel: tube of 30g

What it is

Bionect[®] is a wound-healing agent used to treat wounds and cutaneous ulcers.

Marketing Authorisation Holder

Med. Pharma. CO., LTD

Manufacturer and final Controller

Fidia Farmaceutici S.p.A. - Via Ponte della Fabbrica 3/A - 35031 Abano Terme (PD) - Italy

Why it is used

Bionect® stimulates the repair and regeneration of the skin, aiding the healing of abrasions, excoriations, superficial wounds, scalds, mild burns.

Bionect® is also indicated in localized outbreaks of sore skin caused by physical agents such as the sun, cold, wind and nappy rash, and in irritated and dry skin caused by radiotherapy treatments. Bionect® can also be used as an aid in treatment for cutaneous ulcers of vascular origin, and

slow-healing wounds such as bedsores.

When it must not be used

Hypersensitivity to its components or other strictly related substances from a chemical point of view.

What to do during pregnancy and breastfeeding

Bionect®can be used by pregnant and nursing mothers.

Precautions

Cleanse and disinfect the area to be treated before applying Bionect®.

What medical products or foodstuffs may modify the effect of Bionect®

No phenomena of interaction between Bionect® and antibiotics or other local treatments have ever been reported.

If you are using other medical products, ask the advice of your doctor.

It is important to know that

Use of the product, especially if prolonged, may give rise to sensitization phenomena. Should this occur, consult your doctor before continuing the treatment.

The product does not interfere with the user's ability to drive or use machinery.

How to use the product

Cleanse and disinfect the wound carefully before applying Bionect[®]. Treat the wound 2-3 times a day. Applying enough product to cover the entire area evenly.

What to do if you have used too much

No manifestations of intoxication due to overdose of Bionect[®] have ever been reported. The product is for external use only. In the case of accidental ingestion of an overdose of Bionect[®], consult your doctor immediately or contact your nearest hospital.

Undesirable effects

No systemic-type undesirable effects associated with Bionect[®] have even been reported. Occasional reactions of a local type have been recorded, but they were always mild and resolved spontaneously. Use of the product, especially if prolonged, may give rise to sensitization phenomena. Following the instructions given in the package insert will reduce the risk of any undesirable effects.

Should any such effects occur, however, it is advisable to consult your doctor. It is important to inform your doctor of any undesirable effects that are not described in the package insert.

Expiry and storage

The expiration date indicated on the packaging refers to unopened product that has been correctly stored.

WARNING: do not exceed the recommended doses without consulting a doctor. Do not use the product after the expiration date indicated on the packaging. Keep out of the reach of children.