



Berotec[®] Liquid 0.5 mg/ml

[Fenoterol hydrobromide]

Composition

Each ml contains 0.5 mg
1-(3,5-Dihydroxy-phenyl)-2-[(1-(4-hydroxy-benzyl)-ethyl)-amino]-ethanol hydrobromide (= fenoterol hydrobromide)

Properties

Berotec is used in the treatment and prevention of bronchospasm in bronchial asthma and bronchitis. Berotec relieves all forms of bronchospasm and protects against all bronchoconstrictor stimuli including allergens and cigarette smoke. Berotec is distinguished by its rapid onset and long duration of action on the bronchial muscles. Although Berotec is an extremely long-acting bronchodilator, as with other bronchodilators, the duration of effect varies with the severity of the condition. The usual duration of effect is approximately 8 hours, but may be longer in milder asthmatics (up to 12 hours) and shorter in severe asthmatics (as short as 4 hours). Due to the bronchial selectivity of Berotec, systemic side effects are unlikely. Berotec is thus particularly well tolerated even in long-term treatment. The various forms of administration make it possible to adapt treatment according to the form of the disorder. Berotec tablets and liquid are suitable for long-term treatment to reduce susceptibility to attack and tendency to dyspnoea.

Indications

For the prophylaxis and treatment of bronchospasm in bronchial asthma, obstructive bronchitis, chronic bronchitis, emphysema and bronchopulmonary disorders with bronchospasm.

Dosage and administration

Should be used under physician's prescription.
The individual dosage is determined by the physician before commencement of treatment; patients should be kept under medical observation during treatment. The dosage can be increased or reduced according to the individual response and the severity of the disease.

Liquid 2.5 mg/5 ml

Adults:	5-10 ml 3 times daily
School children 6-14 years:	5 ml 3 times daily
Small children 1-6 years:	2.5-5 ml 3 times daily
Infants up to 1 year:	2.5 ml 2-3 times daily.

Berotec liquid can be used by patients with diabetes without restriction of diet.
The dosage recommendations for children are based on a total daily dose of 0.05-0.15 mg per kg body weight.
The oral forms of Berotec should preferably be taken before meals.

Contra-indications

Hyperthyroidism, subvalvular aortic stenosis, tachyarrhythmia.

Precautions

Other sympathomimetic bronchodilators should only be used with Berotec under strict medical supervision. Anticholinergic bronchodilators may, however, be inhaled at the same time. As with all other drugs, the customary precautions should be observed for Berotec during pregnancy, and the inhibitory effect of Berotec on uterine contraction should be taken into account. Special caution should be exercised if MAO-inhibitors have recently been, or are being concurrently, prescribed. Caution is advised in patients with an unbalanced diabetic metabolism. Use of the oral dosage forms of Berotec in patients with recent myocardial infarction and/or severe organic heart or vascular disorders — especially in doses exceeding the recommended levels — should only be undertaken upon medical advice.

Side effects

Berotec is well tolerated. Fine tremor of the fingers, restlessness, or palpitation may occur. Dizziness, fatigue, headache, sweating, dryness of the mouth and ventricular disturbances or angina pectoris have also been observed. If these side effects occur the dose should be reduced.

Interactions

β -adrenergics, anticholinergics and derivatives of xanthine may intensify the action of Berotec.
 β -receptor blockers antagonize the effect.

Note

If therapy does not produce the desired effect, then the pathological condition is not responding sufficiently well to therapy because of the involvement of other factors. Medical advice should therefore be sought in order that a new plan of treatment can be determined.
Berotec should only be used by children on medical advice and under the supervision of an adult.

Overdosage

Symptoms

Flushing, tremor of the fingers, nausea, tachycardia, increase in systolic blood pressure, fall in diastolic blood pressure, anxiety, excitation and possibly extrasystoles may occur following overdoses.

Treatment

Administration of sedatives, tranquilizers, in severe cases intensive therapy.
 β -receptor blockers, preferably β_1 -receptor blockers, are suitable as specific antidote; however, a possible increase in bronchial obstruction must be taken into account and the dose should be adjusted carefully in patients suffering from bronchial asthma.

Availability

Liquid 0.05%: packs of 30 – 4,000 ml.
A measuring cup graduated from 1 – 6 ml is provided with each bottle.
Store in safe place out of the reach of children.
Store below 25°C.



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