Dilator®

Bambuterol Hydrochloride
Tablet / Oral solution

DESCRIPTION

Dilator® is a preparation of Bambuterol Hydrochloride. It is an oral long-acting ß2- agonist for once-daily treatment of the symptoms of asthma (Bambuterol is not intended to treat acute asthma attacks), particularly in patients who are unable to use inhaled products (such as children and the elderly). Bambuterol is a pro-drug of terbutaline that is slowly converted in the body to the active form, thus providing a prolonged action.

INDICATIONS

- Chronic bronchial asthma, especially for prevention of nocturnal asthma symptoms
- Bronchospasm (breathing difficulties due to the narrowing of the airways)
- Chronic obstructive airways disease

DOSAGE AND ADMINISTRATION

Adult: 20 mg once daily at bed-time is effective if patient has been previously tolerated with ß2- agonist stimulants; other patients, initially 10 mg once daily at bed-time. increased if necessary after 1-2 weeks to 20 mg once daily.
In patients with an impaired renal function (GFR ≤ 50 mL/min) the recommended starting dose is 5 mg, which may be increased to 10 mg after one to two weeks, depending on the clinical effect.

Children 2-5 years: The recommended normal dose is 5 mg (5 mL) once daily.
Children 6-12 years: The recommended initial dose is 5 mg (5 mL) once daily. The dose may be increased to 10 mg (10 mL) after 1 to 2 weeks, depending an the clinical effect.

Elderly: Same as adult dose.

Significant hepatic dysfunction: Not recommended because of unpredictable conversion to terbutaline.

CONTRAINDICATIONS

Hypersensitivity to any components of this product or to terbutaline.

USE IN PREGNANCY & LACTATION

Pregnant women: There is no definite evidence of ill consequence during pregnancy. Nevertheless, the drug should not be used during the first trimester of pregnancy, unless the expected benefit is thought to outweigh any possible risk to the foetus.

Lactating mother: It is excreted in breast milk. So, patients taking this drug should not breast-feed.

SIDE-EFFECTS

Fine tremor (usually hands), nervous tension, headache, peripheral vasodilatation, palpitations, tachycardia; rarely muscle cramps; hypersensitivity reactions including paradoxical bronchospasrn, urticeria and angioedema are reported.

WARNING

Care should be taken with patients suffering trom myocardial insufficiency or thyrotoxicosis. Due to the hyperglycaemic effects of ß2- stimulants additional blood glucose measurements are recommended initially when bambuterol therapy is commenced in diabetic patients. Due to positive inotropic effects of ß2- agonists these drugs should not be used in patients with hypotrophic cardiomyspathy.

DRUG INTERACTION

Bernbuterol inhibits plasma cholinesterases and can prolong the action of drug such as suxamethonium that is inactivated by these enzymes. Bambuterol may partly or totally inhibit the effect of ß-blockers.

PRECAUTIONS

Reduce the dose in renal impairment, avoid in cirrhosis and severe hepatic impairment. Caution should be observed in patients with severe cardiovascular disorder, such as Ischaemic heart disease, tachyarrhythmias or severe heart failure.

PHARMACEUTICAL PRECAUTIONS

Keep away from light and moisture. Keep out of reach of children.

PACKAGING

Dilator® 10 mg tablet : Box containing 10 strips of 10 tablets each. Each tablet contains Bambuterol Hydrochloride BP 10 mg.

Dilator® 20 mg tablet : Box containing 10 strips of 10 tablets each. Each tablet contains Bambuterol Hydrochloride BP 20 mg.

Dilator® oral solution : Bottle containing 60 mL oral solution. Each 5 mL contains Bambuterol Hydrochloride BP 5 mg.

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