

Brizy®

Levosabutamol Tablet/ Syrup

DESCRIPTION

Brizy® is a single isomer β_2 agonist that differs from racemic salbutamol by elimination of (S)-salbutamol. Levosabutamol is an effective bronchodilator whose primary mechanism of action is unimpeded by (S)-salbutamol. Thus, when compared with racemic salbutamol, clinically comparable bronchodilation can be achieved with doses that substantially lessen beta-mediated side effects.

INDICATION

Brizy® is indicated for the treatment and prevention of bronchospasm in adults, adolescents and children over 6 years of age with reversible obstructive airway disease.

DOSAGE AND ADMINISTRATION

Brizy® tablet:

Adults and adolescents above 12 years: 1 - 2 mg three times a day.

Children (6 - 11 years): 1 mg three times a day.

Brizy® syrup:

Adults and adolescents above 12 years: 5 - 10 mL three times a day.

Children (6 - 11 years): 5 mL three times a day.

CONTRAINDICATION

Hypersensitivity to any of the components of the formulation.

PRECAUTIONS

Potentially serious hypokalemia may result from β_2 agonist therapy. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, steroids and diuretics. Serum potassium levels should be monitored in such situations.

Levosabutamol, like all other beta-adrenergic agonists, can produce a clinically significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure. Although such effects are uncommon after administration of levosabutamol at recommended doses, if they occur, the drug may need to be discontinued. Oral levosabutamol should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias or hypertension.

USE IN PREGNANCY AND LACTATION

The use of levosabutamol in pregnant women or lactating mothers should be considered only if the expected benefit to the mother outweighs the possible risk to the fetus or the infant.

It is not known whether levosabutamol is excreted in human milk. Caution should be exercised when oral levosabutamol is administered to nursing mother.

DRUG INTERACTIONS

Other short-acting sympathomimetic bronchodilators or epinephrine should be used with caution with levosabutamol. If additional adrenergic drugs are to be administered by any route, they should be given with caution to avoid deleterious cardiovascular effects.

SIDE-EFFECTS

Potentially serious hypokalemia may result from β_2 agonist therapy. This effect may be potentiated by hypoxia. Particular caution is advised in severe asthma, with monitoring of serum potassium levels. Other side effects such as palpitation, fine tremors of the skeletal muscle (particularly the hand) and muscle cramp may occur. The other likely side effects are gastrointestinal disturbances such as nausea, vomiting, burning substernal or epigastric pain and diarrhoea. In some cases nervousness, headache, fatigue and sleeplessness may occur.

OVERDOSAGE

The expected symptoms with overdosage are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the symptoms listed under side effects e.g. tachycardia, nervousness, headache, tremor, nausea, dizziness, fatigue and sleeplessness. Hypokalemia also may occur.

Treatment consists of discontinuation of oral levosabutamol together with appropriate symptomatic therapy. In the event of serious poisoning, the stomach should be emptied and, if necessary, a beta-blocker should be administered with caution in patients with a history of bronchospasm.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Brizy® 1 tablet : Box containing 5 strips of 10 tablets each. Each tablet contains levosabutamol sulfate INN equivalent to levosabutamol 1 mg.

Brizy® 2 tablet : Box containing 5 strips of 10 tablets each. Each tablet contains levosabutamol sulfate INN equivalent to levosabutamol 2 mg.

Brizy® syrup : Bottle containing 60 mL & 100 mL syrup. Each 5 mL syrup contains levosabutamol sulfate INN equivalent to levosabutamol 1 mg.

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Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

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PM00075 V04