

BUTALIN

Bronchodilator Sugar-Free Syrup, Tablets

Composition

BUTALIN Sugar-Free Syrup

Each teaspoonful (5mL) contains:

Active ingredient: Salbutamol sulphate equivalent to salbutamol 2mg.

Excipients: Sodium citrate, saccharin sodium, sodium chloride, citric acid, sodium benzoate, hypromellose, hydroxyethylcellulose, tangerine flavour, strawberry flavour, and purified water.

BUTALIN 2mg Tablet

Each tablet contains:

Active ingredient: Salbutamol sulphate equivalent to salbutamol 2mg.

Excipients: Lactose, starch, FD&C yellow no. 6 (sunset yellow), and magnesium stearate.

BUTALIN 4mg Tablet

Each tablet contains:

Active ingredient: Salbutamol sulphate equivalent to salbutamol 4mg.

Excipients: Lactose, starch, FD&C red no. 3, and magnesium stearate.

Properties

Salbutamol, the active ingredient of **BUTALIN**, is the safest selective beta₂-adrenergic agonist that produces marked bronchodilation with minimal effects on the cardiovascular system. It acts by stimulating beta₂-adrenergic receptors in the lungs to relax bronchial smooth muscle, thereby relieving bronchospasm.

BUTALIN is rapidly and well absorbed as its action starts within 30 minutes of administration, while the time to peak concentration is 2 hours for the syrup and 2 - 3 hours for the tablets. Its duration of action is 4 - 8 hours. The elimination half-life is 3.8 - 6 hours as 69 - 90% is renally eliminated while only 4% is fecally eliminated.

Indications

BUTALIN is indicated for the treatment of bronchial asthma and reversible airways obstruction associated with bronchitis, pulmonary emphysema, bronchiectasis, and other pulmonary diseases.

Dosage

Adults

The usual recommended dose is 2 - 4 mg 3 - 4 times daily.

Children

6 - 12 years: 2mg (1 teaspoonful or a 2mg tablet), 3 - 4 times daily.

2 - 6 years: 1- 2mg (½ - 1 teaspoonful), 3 - 4 times daily.

Notes

- Elderly and patients sensitive to beta-adrenergic stimulation are better to receive an initial dose of 2mg 3 - 4 times daily, increased gradually as needed and tolerated.
- For adults and children above 12 years of age, a dosage above 4mg 4 times a day should be used only when the patient fails to respond. If a favorable response does not occur with the 4mg initial dose, it should be cautiously increased stepwise up to a maximum of 8mg 4 times a day as tolerated.

Contraindications

This preparation should be avoided by patients who are hypersensitive to salbutamol or any of the other components.

Precautions

Salbutamol should be given with caution in patients suffering from hyperthyroidism or from cardiovascular disease, especially arrhythmias and hypertension, as well as in those susceptible to QT-interval prolongation.

Great care should also be exercised in patients with diabetes mellitus as blood glucose should be carefully monitored.

Pregnancy: Although salbutamol may be indicated for premature labour during the third trimester of pregnancy, its administration should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus.

Lactation: As salbutamol is probably secreted in breast milk, its use during lactation should be restricted to situations where the expected benefit to the mother is likely to outweigh any potential risk to the neonate.

Side Effects

Some patients may experience fine tremor, particularly in the hands, which is dose-related and usually common with all beta₂-adrenergics including salbutamol.

Other less frequent side effects include nervous tension, headache, peripheral dilatation, and palpitations.

Rarely, arrhythmias, which occur usually in susceptible patients, as well as tachycardia have been reported.

Very rarely, muscle cramps and hypersensitivity reactions including paradoxical bronchospasm, urticaria, and angioedema have been reported.

With high doses, as with other beta₂-agonists, hypokalaemia may occur.

As with other beta₂-agonists, children may rarely experience sleep and behavioral disturbances.

Overdosage

Upon accidental overdosage, induction of emesis along with gastric lavage should be performed immediately. A cardioselective beta-adrenergic blocker can be used, but with great caution, especially in patients having a history of bronchospasm.

Drug Interactions

Concurrent administration of salbutamol with beta-adrenergic blocking agents including ophthalmic agents may result in mutual inhibition of therapeutic effects.

Increased risk of hypokalemia may occur upon concurrent administration of high doses of salbutamol with theophylline, acetazolamide, loop diuretics, thiazides, or thiazide-related diuretics, as well as with high doses of corticosteroids, however, interactions do not generally apply to topical corticosteroids including inhaled corticosteroids.

Presentations

BUTALIN sugar-free syrup: Bottles of 120mL.

BUTALIN 4mgTablets: Packs of 20 tablets. Hospital packs of 1000 tablets.

BUTALIN 2mgTablets: Packs of 20 tablets. Hospital packs of 500 or 1000 tablets.

* Store at room temperature not exceeding 25°C. Protect the syrup from light. Keep the tablets in a dry place.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medications out of the reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.

Any information ? Call Our Toll Free No. (971) 800-4994



Produced by: **juphar**
Gulf Pharmaceutical Industries,
Ras Al Khaimah, U. A. E.

