

Sultolin[®] Cozycap

Salbutamol BP

COMPOSITION

Sultolin[®] Cozycap : Each Cozycap contains Salbutamol BP 200 microgram.

INDICATION

Sultolin[®] Cozycap is indicated both for treatment and prophylaxis of bronchospasm in bronchial and exercise-induced asthma in patients 4 years of age and older, and also for treatment of other conditions, such as bronchitis and emphysema associated with reversible airways obstruction. This is particularly useful in patients who are unable to use the aerosol form of salbutamol properly or who prefer a powder formulation for inhalation. **Sultolin[®]** Cozycap acts rapidly and may be used when necessary to relieve attacks of acute dyspnea.

DOSAGE AND ADMINISTRATION

Adults: For the relief of bronchospasm and for managing intermittent episodes of asthma, one or two cozycaps may be administered as a single dose. The usual recommended dosage of **Sultolin[®]** Cozycap for inhalation for adults for maintenance or prophylactic therapy is the contents of one 200 microgram capsule every 4 to 6 hours using a revolizer[™] device. In some patients, the contents of two 200 microgram capsules inhaled every 4 to 6 hours may be required. Large doses or more frequent administration is not recommended. The use of salbutamol powder for inhalation can be continued as medically indicated to control recurring/intermittent episodes of bronchospasm.

Children: One **Sultolin[®]** Cozycap is the recommended dose for relief of acute bronchospasm in the maintenance of episodic asthma or before exercise of children 4 years of age and older. One inhalation should be administered for three or four times a day for routine maintenance or prophylactic therapy. This dosage may be increased to inhalation of two cozycaps, if necessary. The bronchodilator effect of each administration of inhaled **Sultolin[®]** cozycap lasts for at least four hours. Such patients should be warned not to increase the dose of inhaler, but should seek medical advice immediately.

Exercise-induced Asthma: Adults - 400 microgram, Child - 200 microgram, 15-30 minutes prior to any physical exertion.

CONTRAINDICATION

Hypersensitivity to any of its components.

PRECAUTION

In the event of a previously effective dose of Salbutamol inhaler, failing to give relief for at least three hours, the patients should be advised to seek medical advice. Salbutamol and other β_2 agonists should be given with caution in hyperthyroidism, myocardial insufficiency, arrhythmias, susceptibility to QT interval prolongation, hypertension, and diabetes mellitus.

SIDE EFFECT

Salbutamol may cause fine tremor of skeletal muscle (particularly of the hands), palpitations, and muscle cramps. Tachycardia, headache, and peripheral vasodilatation have been reported after large dose. They usually disappear with continued treatment.

Hypersensitive reactions including angioedema and urticaria, bronchospasm, hypotension and collapse have been reported very rarely. As with all inhalation therapy, the potential for paradoxical bronchospasm should be kept in mind. If it occurs, the preparation should be discontinued immediately and alternative therapy should be instituted.

USE IN PREGNANCY AND LACTATION

Inhalation has particular advantage as a mean of administration of β_2 agonist during pregnancy as the therapeutic action can be achieved without the requirement for such plasma concentration liable to have a pharmacological effect on the fetus. Although there is no evidence that salbutamol is teratogenic, it should be used in the first trimester only if absolutely essential. Salbutamol probably enters breast milk, but the concentration is unknown. However, no adverse effects have been reported in the breast-fed babies of mothers taking the drug by inhalation.

PHARMACEUTICAL PRECAUTION

- Cozycaps must not be swallowed.
- Don't exceed the recommended dose.
- Keep the container tightly closed.
- Keep away from light and moisture, store in cool and dry place.
- Insert the cozycap in the revolizer[™] just prior use, as Cozycap exposed to moisture may not tear easily.

HOW SUPPLIED

Sultolin[®] Cozycap: Each pack contains 30 cozycaps in alu-alu blister.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH