



Sultolin® Cozycap

Salbutamol
Bronchodilator inhalant

COMPOSITION

Sultolin® Cozycap : Each Sultolin® Cozycap contains Salbutamol BP 200 µg

INDICATION

Sultolin® Cozycap for inhalation is indicated both for treatment and prophylaxis/prevention 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 with associated reversible airways obstruction. This is particularly useful in patients who are unable to properly use the aerosol form of salbutamol or who prefer a powder formulation for inhalation.

Sultolin® Cozycap acts rapidly and may be used when necessary to relieve attacks of acute dyspnea. Doses may be given prophylactically before any physical exertion to prevent Exercise-induced asthma. Because of its selective action on bronchi and its lack of effects on the cardiovascular system, Sultolin® Cozycap is indicated for treating bronchospasm in patients with co-existing heart diseases or hypertension.

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 µg capsule every 4 to 6 hours using a Cozyhaler device. In some patients, the contents of two 200 µg 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. During this time, most patients gain optimal benefit from regular use of the salbutamol powder for inhalation.

Children: One Sultolin® cozycap is the recommended dose for relief of acute bronchospasm in the maintenance of episodic asthma or before exercise of children 5 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.

For optimum results it should be used regularly. The bronchodilator effect of each administration of inhaled Sultolin® cozycap lasts for at least four hours,

Sultolin® Cozycap

except in patients whose asthma is becoming worse. Such patients should be warned not to increase the dose of inhaler, but should seek medical advice immediately.

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

CONTRAINDICATION AND PRECAUTION

Sultolin® cozycap is contraindicated in patients with a history of hypersensitivity to any of its components.

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 in order that any necessary additional steps may be taken. Salbutamol and other beta₂ agonists should be given with caution in hyperthyroidism, myocardial insufficiency, arrhythmias, susceptibility to QT interval prolongation, hypertension, and diabetes mellitus.

In severe asthma, particular caution is also required to avoid inducing hypokalaemia as this effect may be potentiated by hypoxia or by concomitant administration of other anti-asthma drugs: beta₂ agonists such as salbutamol are not appropriate for use alone in the treatment of severe asthma.

Salbutamol and non-selective β-blockers such as Propranolol should not be prescribed together. Inhaled Salbutamol preparations are not appropriate for managing premature labor and also should not be used for threatened abortion during the first or second trimester of pregnancy.

SIDE EFFECT

Salbutamol is generally well tolerated and serious toxicologic effects are few. Salbutamol may cause fine tremor of skeletal muscle (particularly of the hands), palpitations, and muscle cramps. Tachycardia, tenseness, headaches, 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.

Sultolin® Cozycap

USE IN PREGNANCY AND LACTATION

Inhalation has particular advantage as a mean of administration of beta₂ agoniss 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.

OVERDOSAGE

The preferred antidote for overdosage with sulbutamol dry powder inhaler is cardioselective beta-blocker, such as metoprolol tartarate. But beta-blockers should be used with caution in patients with a history of bonchospasm.

STORAGE CONDITION

- Store in a cool place away from heat & moisture
- Keep the container tightly closed
- Insert the COZYCAP in the COZYHALER just prior to use, as COZYCAP exposed to moisture may not break open easily.

HOW SUPPLIED

Sultolin® cozycap : Box containing 30 capsules in moisture proof container.

