

SALBUTIS INHALER 100mcg/dose

CFC-free

NAME

Salbutamol Inhalation Aerosol BP CFC-free

STRENGTH

200 doses, each dose contains 100mcg Salbutamol BP and 4.5mg Absolute ethanol

300 doses, each dose contains 100mcg Salbutamol BP and 4.5mg Absolute ethanol

400 doses, each dose contains 100mcg Salbutamol BP and 4.5mg Absolute ethanol

DOSAGE FORM

Aerosol

PRODUCT DESCRIPTION

Salbutamol Inhalation Aerosol is a kind of white or slight yellow suspension mixed with just right quantity of propellant and kept in a pressurised canister with a metered valve system.

PHARMACODYNAMICS

Salbutamol is a selective β_2 -adrenoceptor agonist. At therapeutic doses it acts on the β_2 -adrenoceptors of bronchial muscle providing short acting (4-6 hours) bronchodilatation with a fast onset (within 5 minutes) in reversible airways obstruction.

PHARMACOKINETICS

The inspired aerosol's effect begins to act in 5 minutes and results in maximum plasma concentrations occurring within 2 to 4 hours. The total effective period lasts for 4-6 hours. Salbutamol has an elimination half-life of 3-8 hours. Approximately 72% of the inhaled dose is excreted within 24 hours in the urine, and consists of 28% as unchanged drug and 44% as metabolite.

INDICATION

Salbutamol Inhalation Aerosol provides short-acting (4 to 6 hours) bronchodilatation with fast onset (within 5 minutes) in reversible airways obstruction.

It is particularly suitable for the relief and prevention of asthma symptoms. It should be used to relieve symptoms when they occur, and to prevent them in those circumstances recognised by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure).

Salbutamol Inhalation Aerosol is particularly valuable as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction and use of regular inhaled corticosteroid therapy.

RECOMMENDED DOSE

In acute bronchospasm:

Adult dosage : 100 to 200 mcg daily.

Children dosage: 100 mcg daily. If required, the dose can be increased to 200mcg.

Prevention of exercise-induced bronchospasm:

Adult dosage: 200mcg daily before exertion.

Children dosage: 100 mcg daily before exertion. If required, the dose can be increased to 200mcg.

In Chronic therapy:

Adult dosage: Up to 200mcg four times daily.

Children dosage: Up to 100mcg four times daily.

ROUTE OF ADMINISTRATION

Oral inhalation.

CONTRAINDICATION

Although intravenous salbutamol, and occasionally salbutamol tablets, are used in the management of premature labour uncomplicated by conditions such as placenta praevia, ante-partum haemorrhage or toxoemia of pregnancy, inhaled salbutamol preparations are not appropriate for managing premature labour. Salbutamol preparations should not be used for threatened abortion.

Salbutamol Inhalation Aerosol is contra-indicated in patients with a history of hypersensitivity to any of the components.

WARNING AND PRECAUTIONS

1. It should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus; and in patients who are unusually responsive to sympathomimetic amines.
2. The daily dosage must be controlled, if the therapeutic effect is not evident, the other therapies should be considered.
3. It will develop tolerance in a prolonged administration period.
4. It is not appropriate to take such β adrenergic blocking agents as propranolol while using Salbutamol Aerosol.
5. The canister is pressurised. Do not incinerate or expose to heat. Do not puncture even when empty.

DRUG INTERACTIONS

Salbutamol and non-selective β -blocking drugs such as propranolol, should not usually be prescribed together.

PREGNANCY AND LACTATION

Please use it as the instruction of the patient's physician.

Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus. As with the majority of drugs, there is little published evidence of the safety of salbutamol in the early stages of human pregnancy, but in animal studies there was evidence of some harmful effects on the fetus at very high dose levels. A full range of reproductive studies with the non-chlorofluorocarbon propellant HFA 134a, have shown no effect on fetal development in animals.

Specific teratology studies with Salbutamol Inhalation Aerosol have shown no effects over and above those consistent with the known effects of high doses of beta-agonists. However, there is no experience on use in pregnancy and lactation in humans.

As salbutamol is probably secreted in breast milk, its use in nursing mothers requires careful consideration. It is not known whether salbutamol has a harmful effect on the neonate, and so its use should be restricted to situations where it is felt that the expected benefit to the mother is likely to outweigh any potential risk to the neonate.

SIDE EFFECTS

Xerostomia, cough, vomiting, Dizziness and palpitation.

SYMPTOMS AND TREATMENT OF OVERDOSE

The expected symptoms with overdosage are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the symptoms listed under ADVERSE REACTIONS, e.g.: seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, and sleeplessness.

Hypokalemia may also occur.

The preferred antidote for overdosage with salbutamol is a cardioselective β -blocking agent, but β -blocking drugs should be used with caution in patients with a history of bronchospasm.

STORAGE CONDITION

Store below 30°C.

Protect from frost and direct sunlight.

As with most inhaled medications in aerosol canister, the therapeutic effect of this medication may decrease when the canister is cold.

The canister should not be broken, punctured or burnt, even when apparently empty.

SHELF LIFE

36 months.

MANUFACTURER

Jewim Pharmaceutical (Shandong) Co., Ltd. Taian, PRC

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HOW TO USE YOUR INHALER PROPERLY



- 1) Remove the cover from the mouthpiece and shake the inhaler vigorously.
- 2) Holding the inhaler as shown, breathe out gently (but not fully) and then immediately.
- 3) Place the mouthpiece in the mouth and close your lips around it. After starting to breathe in slowly and deeply through your mouth, press the inhaler firmly, as shown, to release it and continue to breathe in.
- 4) Hold your breath for 10 seconds, or as long as is comfortable, before breathing out slowly.
- 5) If you are to take a second inhalation you should wait at least one minute before repeating steps 2, 3 and 4.
- 6) After use, replace the cover on the mouthpiece.