

Brodil[®]

Inhalation Aerosol

Salbutamol

Description

Brodil[®] Inhaler is preparation of Salbutamol which is a short-acting selective beta-2 adrenoceptor agonist. Salbutamol is a sympathomimetic agent which has a highly selective action on beta adrenergic receptors in bronchial smooth muscle, thereby causing relaxation of bronchial smooth muscle fibers. This action results in improved pulmonary function as demonstrated by spirometric measurements. At therapeutic doses, salbutamol has little or no action on the beta-1 adrenergic receptors in cardiac muscle. It is used in the treatment of asthma and other forms of diffuse reversible airways obstruction.

Indications

Brodil[®] Inhaler is indicated for the prophylaxis and treatment of bronchial asthma and for the treatment of reversible airways obstruction associated with bronchitis and emphysema.

Brodil[®] Inhaler may be used to relieve attacks of acute dyspnoea and may also be taken prophylactically before exertion or to prevent exercise induced asthma.

Brodil[®] is suitable for treating bronchospasm in patients with coexisting heart disease or hypertension, including those taking beta blockers, because of its selective action on the bronchial receptors and lack of effects on the cardiovascular system.

Dosage and Administration

Brodil[®] Inhaler should be administered by the oral inhaled route only. Shake **Brodil[®]** Inhaler well before each spray.

Adults

- For the relief of acute bronchospasm and for managing intermittent episodes of asthma: one or two 2 puffs may be administered as a single dose.
- For chronic maintenance or prophylactic therapy: two puffs 3 or 4 times daily.
- For prevention of exercise induced bronchospasm: two puffs should be taken at least 15 minutes before exertion.

Children

For relief of acute bronchospasm in the maintenance of episodic asthma or before exercise: one 1 puff may be administered as a single dose.

For routine maintenance and prophylaxis therapy: one 1 puff three or four times daily, increasing if necessary to two puffs three or four times daily.

Elderly

The dosage is the same as that for adults.

Side Effects

Mild tremor and headache have been rarely reported. These usually disappear with continuous treatment. There have been very rare reports of transient muscle cramp. Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse have been reported very rarely. As with other 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.

Warnings

The management of asthma should normally be a stepwise programme, and patient response should be monitored clinically and by lung function test. Increasing use of short-acting inhaled beta-2 agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed. Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted. In the event of a previously effective dose of inhaled salbutamol failing to give relief for at least three hours, the patient should be advised to seek medical advice in order that any necessary additional steps may be taken. Patients' inhaler technique should be checked to make sure that aerosol actuation is synchronized with inspiration of breath for optimum delivery of the drugs to the lungs.

Precautions

Salbutamol should be administered cautiously to patients suffering from thyrotoxicosis. In the event of previously effective dose of Salbutamol inhaler failing to give relief for at least three hours, the patient should be advised to seek medical advice in order that any necessary additional steps may be taken.

Pregnancy and lactation

Salbutamol is known to cross the placental barrier in humans. Safety for use in pregnancy has not been demonstrated, therefore the drug should not be used in pregnant women, or those likely to become pregnant, unless the expected benefit outweighs any potential risk. Oral administration of salbutamol to rats and rabbits during pregnancy showed no teratogenic effects in offspring, but evidence of retardation of fetal development was recorded in an inhalational teratology study in rabbits at an estimated dose of 149 µg/kg/day. Although intravenous salbutamol and occasionally salbutamol tablets are used in the management of uncomplicated premature labour, Salbutamol presentations should not be used for threatened abortion during the first or second trimesters of pregnancy. Intravenous salbutamol is contraindicated in cases of ante-partum haemorrhage because of the risk of further haemorrhage from an atonic uterus and there is the risk of the same problem arising inadvertently in asthmatics using salbutamol. Profuse uterine bleeding following spontaneous abortion has been reported after the use of salbutamol. Special care is required in pregnant diabetic women. As salbutamol is probably secreted in breast milk, its use in nursing mothers is not

recommended unless the expected benefit to the mother is greater than any possible risk to the infant.

Contraindications

Salbutamol inhaler is contraindicated in patients with a history of hypersensitivity to any of its components. Although intravenous Salbutamol, and occasionally Salbutamol tablets, is used in the management of premature labour uncomplicated by conditions such as placenta praevia, ante-partum haemorrhage or toxemia of pregnancy, Salbutamol inhaler preparations are not appropriate for managing premature labour. Salbutamol preparation should not be used for threatened abortion during the first or second trimesters of pregnancy.

Drug interaction

Salbutamol should be administered with caution to patients being treated with monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants, since the action of salbutamol on the vascular system may be potentiated. The effects of salbutamol are inhibited by beta antagonists such as propranolol. Other sympathomimetic aerosol bronchodilator should not be used concomitantly with salbutamol. If additional adrenergic drugs are to be administered by any route, they should be used with caution to avoid deleterious cardiovascular effects. Treatment with diuretics may augment the hypokalemia that occurs with large doses of salbutamol.

Overdosage

As with all sympathomimetic aerosol medications, cardiac arrest and even death may be associated with abuse. The preferred antidote for overdose with salbutamol inhaler is cardioselective beta-blocker, such as metoprolol tartarate. But beta-blockers should be used with caution in patients with a history of bronchospasm. Dialysis is not appropriate treatment for overdose of salbutamol inhalation aerosol.

Pharmaceutical Precaution

Do not puncture, break or incinerate pressurized canister even when apparently empty.

Avoid storage in direct sunlight or heat.

Store below 30°C.

Keep away from eyes.

Keep away from children.

Package quantities

Brodil® Inhaler: Each canister contains 200 measured doses, each containing 100 micrograms of Salbutamol BP.

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