

Metered aerosol delivering 100 mcg Salbutamol BP per actuation with a special actuator

USES

Salbutamol BP is a beta-adrenergic stimulant which has a highly selective action on the receptors in bronchial muscle and in therapeutic dosage, little or no action on the cardiac receptors.

Salbutamol is also highly active in preventing antigen-induced release of histamine and slow-reacting substance of anaphylaxis SRS-A, from mast cells in human lung sensitised with IgE antibody. Such Type I hypersensitivity reactions are generally considered to be the primary triggers of the allergic asthma syndrome.

BUTOVENT[®] is, therefore, indicated both for the treatment and prophylaxis of bronchial asthma, and also for the treatment of other conditions, such as bronchitis and emphysema, with associated reversible airway obstruction. Because BUTOVENT[®] is long-acting it is ideally suited for routine maintenance therapy in chronic asthma and chronic bronchitis. The inhaler drug-delivery system, using salbutamol in microgram dosage, avoid the skeletal muscles tremor sometimes associated with oral therapy.

BUTOVENT[®] acts rapidly and may be used when necessary to relieve attacks of acute dyspnoea. Doses may be taken prophylactically before exertion or to prevent exercise-induced asthma.

Because of its selective action on the bronchi and its lack of effects on the cardiovascular system, BUTOVENT[®] is suitable for treating bronchospasm in patients with co-existing heart disease or hypertension, including those taking beta-blocking drugs which often impair respiratory function.

DOSAGE AND ADMINISTRATION

Adults: for the relief of acute bronchospasm and for managing intermittent episodes of asthma, one or two inhalations may be administered as a single dose. The recommended dose for chronic maintenance or prophylactic therapy is two inhalations three or four times a day.

To prevent exercise-induced bronchospasm, two inhalations should be taken before exertion.

Children: one inhalation is the recommended dose for the relief of acute bronchospasm, in the management of episodic asthma or before exercise.

One inhalation should be administered three or four times a day for routine maintenance or prophylactic therapy. These doses may be increased to two inhalations, if necessary.

For optimum results, in most patients, BUTOVENT[®] should be used regularly.

The bronchodilator effect of each administration of inhaled BUTOVENT[®] lasts at least four hours except in patients whose asthma is worsening. Such patients should be warned not to increase their usage of inhaler but should seek medical advice in case treatment with a glucocorticoid is indicated.

PRECAUTIONS

In the event of a previously effective dose of BUTOVENT[®] failing to give relief lasting for at least three hours, the patient should be advised to seek medical advice in order that any necessary additional steps may be taken. BUTOVENT[®] should be administered cautiously to patients suffering from thyrotoxicosis. Unnecessary administration of drugs during the first trimester of pregnancy is undesirable.

SIDE-EFFECTS

No important side-effects have been reported following BUTOVENT[®] therapy.

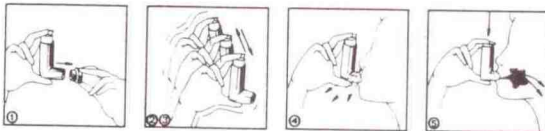
OVERDOSAGE

The preferred antidote for overdosage with BUTOVENT[®] is a cardioselective beta-blocking agent, but beta-blocking drugs should be used with caution in patients with a history of bronchospasm.

STORAGE

BUTOVENT[®] should be stored in a cool place, protected from frost and direct sunlight. The canister should not be broken, punctured or burnt, even when apparently empty.

INSTRUCTIONS FOR USE



- 1) Remove the cap from the mouthpiece.
 - 2) Hold the inhaler as illustrated.
 - 3) Shake the inhaler.
 - 4) Place the mouthpiece well into the mouth, close the lips firmly and make a complete expiration.
 - 5) Start a long and deep inspiration with the mouth, and then press the metal canister downwards only once with the index finger. After inspiration, hold breath as long as you can.
- Wait a few seconds before making another inhalation.
Replace the cap.

The mouthpiece should be kept clean: remove the canister, rinse the mouthpiece in warm water, dry, and replace the canister.

PACKAGE

Metered aerosol with a special actuator. Each canister provides 200 inhalations.



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