

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Ipravent Respirator Solution

Ipravent Respules



Composition

Ipravent Respirator Solution

Each ml contains:

Ipratropium Bromide BP 250 mcg

Ipravent Respules

Each 2 ml respule contains:

Ipratropium Bromide BP equivalent

to Ipratropium Bromide

(anhydrous) 500 mcg

in an isotonic solutionq.s.

Description

Ipratropium bromide is an anticholinergic bronchodilator. It inhibits vagally mediated reflexes by antagonizing the action of acetylcholine, the transmitter agent released from the vagal nerve.

Indications

Ipravent Respirator Solution Respules when used in conjunction with β_2 adrenergic respiratory solution/ Respules such as salbutamol (Asthalin), is indicated for acute asthmatic attacks. **Ipravent** Respirator Solution /**Ipravent** Respules are also indicated for the treatment of acute exacerbations of COPD. It is also indicated as a bronchodilator for maintenance treatment for bronchospasm associated with chronic obstructive pulmonary disease.

Dosage and Administration

Ipravent Respirator Solution

The dosage should be adapted to the individual requirements of the patient. Patients should also be kept under medical supervision during treatment. The recommended dose is to be diluted with physiological saline to a final volume of 3-4 ml and nebulised and inhaled until the solution is consumed. The solution should be rediluted each time before use, any residual solution should be discarded.

The following doses are recommended:

Adults (including the elderly and adolescents over 14 years of age)

0.4 ml 2 ml (100 mcg 500 mcg) three or four times daily.

Children (6-14 years): 0.4 ml - 2 ml (100 mcg - 500 mcg) three or four times daily.

Children (Under 6 years of age): Because there is limited information in this age group, the following dose is recommended, which should be given under medical supervision: 0.4 ml - 1 ml (100 mcg - 250 mcg) three or four times daily.

The dose may be repeated after intervals for at least 2 hours, if required.

Daily doses exceeding 2 mg should be given under medical supervision.

Ipravent Respules

Adults: 500 mcg (one respule) by nebulisation 3-4 times daily; separate doses by 6-8 hours.

Children: Not recommended.

9456 U

Contraindications

Hypersensitivity to atropine or its derivatives.

Warnings and Precautions

Drug Interactions

Anticholinergic effects of some drugs can be enhanced.

Pregnancy

Preclinical studies have shown no hazard but safety during human pregnancy has not yet been established. The usual precautions regarding the use of drugs at this time, especially during the first trimester should be observed.

Nursing Mothers

Safety has not yet been established.

OTHERS

Ipravent Respirator Solution contains the preservative benzalkonium chloride (antimicrobial) and the stabiliser ethylene diamine tetraacetic acid (EDTA).

It has been reported that these components may cause bronchoconstriction in some patients when given in high doses.

Ipratropium bromide is not indicated for the initial treatment of acute episodes of bronchospasm where rapid response is required. The patient should be warned to seek medical advice, when a reduced response becomes apparent during therapy. Caution is generally advocated in the use of anticholinergic agents in patients with narrow-angle glaucoma and urinary outflow obstruction due to prostatic hypertrophy.

It is advisable not to greatly exceed the recommended daily dose during both acute and maintenance treatment.

If therapy does not produce significant improvement or if the patient's condition gets worse, medical advice must be sought in order to determine a new plan of treatment. In the case of acute or rapidly worsening dyspnoea (difficulty in breathing) a doctor should be consulted immediately.

Ipravent Respirator Solution should not be mixed with sodium cromoglycate because mixing produces a white precipitate. This is due to complexation between sodium cromoglycate and the benzalkonium chloride in **Ipravent** Respirator Solution.

Side Effects

In isolated cases there may be local reactions such as dryness of the mouth, throat irritation, or allergic reactions. As with other bronchodilators, in some cases cough, in very rare instances paradoxical bronchoconstriction have been observed. If, by inappropriate handling, the aerosol enters the eyes in patients with narrow-angle glaucoma, a rise of intraocular pressure may occur. In these cases eye drops to induce miosis should be administered.

Overdosage

Other than reversible accommodation disturbances, no symptoms of overdosage have been encountered and in view of the wide therapeutic range and topical administration of **Ipravent**, none are to be expected. If necessary, symptomatic treatment is recommended.

Storage: Store in a cool dry place.

Presentation

Ipravent Respirator Solution

Bottle of 15 ml

Ipravent Respules

Respule of 2 ml

Cipla

9456 U