

New Zealand Data Sheet

Name of Medicine

Univent, respiratory solution

Presentation

Inhalation ampoule: 500 mcg/2 mL, low density polyethylene single dose unit containing clear colourless to almost colourless aqueous solution.

Inhalation ampoule: 250 mcg/1 mL, low density polyethylene single dose unit containing clear colourless to almost colourless aqueous solution.

Uses

Actions

Ipratropium bromide is a parasympathetic inhibitor used for the treatment of chronic reversible obstructive airways disease. It differs fundamentally from the sympathomimetic bronchodilators usually administered by inhalation as it blocks the vagal reflexes, which mediate bronchoconstriction. Ipratropium bromide exerts a local effect on the airways and has a high therapeutic ratio, producing bronchodilation without significant effect on other body systems. Ipratropium bromide is, therefore, very well tolerated and is suitable for use in patients with cardiac or circulatory disorders, thyrotoxicosis and for those patients unacceptably sensitive to, or unresponsive to other bronchodilators.

The onset of action occurs 3-5 minutes after inhalation and the effect on the airways lasts for 5-6 hours.

Pharmacokinetics

The systemic bioavailability after inhalation is very low. As compared with intravenous and oral administration, it amounts to only 5% and 10-30%, respectively. Plasma level behaviour after inhalation is similar to that after oral use. Following inhalation of 0.555mg, the peak plasma concentrations were only 0.06 ng/ml after 3 hours.

The elimination half-life (active ingredient and metabolites) is about 3-4 hours. Renal elimination after intravenous use amounts to about 70% of the labelled dose administered, partly in the form of inactive metabolites. Serum protein binding is less than 20%. There is no transgression of the blood/brain barrier.

Indications

For the short term acute treatment of the reversible component in chronic obstructive airways disease, such as chronic bronchitis and bronchial asthma.

Dosage and Administration

Adults:

The usual dose is 2 mL solution (500 mcg) nebulised and inhaled.

Children:

The usual dose is 1 mL solution (250 mcg) nebulised and inhaled.

The solution should be nebulised over 10 to 15 minutes at a gas flow of 6 to 10 L/minute. Treatment with ipratropium bromide solution may be repeated every 4 to 6 hours as necessary.

Ipratropium bromide is commonly used in combination with a β 2-agonist to maximise bronchodilation.

Recommendations for dilution of the nebuliser solution:

Under the supervision of a medical practitioner (hospital/GP surgery):- solution should be diluted with preservative free sterile Sodium Chloride Inhalation Solution 0.9% to a volume of 3 to 4 mL in nebuliser bowl.

Home Use: do not dilute, unless mixed with a compatible medication described on action plan.

Contraindications

Known sensitivity to atropine-like substance or inactive excipients.

Warnings and Precautions

Use of the nebuliser solution should be subject to close medical supervision during initial dosing. There have been rare reports of paradoxical bronchospasm associated with the administration of ipratropium bromide nebuliser solution. The patient should be advised to seek medical advice should a reduced response become apparent.

Generally, caution is advocated in the use of anticholinergic agents in patients with glaucoma and prostatic hypertrophy, although the risk of complications at therapeutic doses can be considered to be minimal. Patients must be instructed in the correct administration and warned not to allow the solution or mist to enter the eyes.

Use in pregnancy and lactation

As with any medicine, caution should be observed during the first trimester of pregnancy. Safety during lactation has not been established.

Adverse Effects

Anticholinergic side effects are unlikely to occur at therapeutic dosages, however, the potential for systemic adverse effects exists. Adverse effects such as dizziness, blurred vision or other changes in vision may influence the ability to drive or use machines. Some patients may complain of dryness of the mouth or notice a bitter taste. In isolated cases throat irritation or cough has been reported. There is no evidence that in the therapeutic dose range ipratropium bromide has any adverse effect on sputum viscosity or volume.

Urinary retention and constipation have only rarely been reported with ipratropium bromide.

Interactions

Beta-adrenergics and xanthine preparations may enhance the bronchodilatory effect. Anticholinergic effects of other drugs can be intensified.

Overdosage

Accidental overdose by inhalation is unlikely. Cumulative inhaled dose of up to 1.2mg produced no increase in heart rate. Single doses of ipratropium bromide of 30mg by mouth cause anticholinergic side effects but these are not severe and do not require specific reversal. However, should signs of serious anticholinergic toxicity appear, cholinesterase inhibitors may be considered.

Pharmaceutical Precautions

Store below 25°C. Protect from light.

This product contains no preservative. A fresh dose unit should be used for each dose which should be opened immediately before administration. Any remaining solution should be discarded.

Medicine Classification

Prescription Medicine.

Package Quantities

Cartons of 20 inhalation ampoules.

Further Information

Nil

Excipients

Excipients include sodium chloride, hydrochloric acid and purified water.

Name and Address

Rex Medical Ltd
PO Box 18-119
Glen Innes
AUCKLAND.
Ph (09) 574 6060
Fax (09) 574 6070

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