

Sulprex[®]

Salbutamol and Ipratropium Bromide

COMPOSITION

Sulprex[®] Nebuliser Solution: Each 3 ml ampoule contains Ipratropium Bromide (monohydrate) BP equivalent to Ipratropium Bromide 500 microgram and Salbutamol Sulphate BP equivalent to Salbutamol 2.5 mg

INDICATION

The management of bronchospasm in patients suffering from chronic obstructive pulmonary disease.

DOSAGE & ADMINISTRATION

Sulprex[®] Nebuliser Solution may be administered from a suitable Nebuliser or an intermittent positive pressure ventilator.

Adults (including elderly patients and children over 12 years): 1 ampoule three or four times daily.

HOW TO USE

Step 1: Open the packet and remove the blister. Carefully separate an ampoule from the blister.

Step 2: Twist off the top. Always hold the ampoule upright.

Step 3: Squeeze the desired amount of the Nebuliser Solution into the Nebuliser chamber.

Step 4: If dilution is needed follow the doctors instruction.

CONTRAINDICATION

It is contraindicated in patients with hypertrophic obstructive cardio- myopathy or tachyarrhythmia and in patients with hypersensitivity to ipratropium bromide, salbutamol sulphate or to atropine or its derivatives.

PRECAUTION

After administration urticaria, angioedema, rash, bronchospasm and oropharyngeal oedema may occur.

There have been rare reports of ocular complications (i.e. mydriasis, blurring of vision, narrow-angle glaucoma and eye pain) when ipratropium bromide have been come contact of the eye.

Patients must be instructed in the correct use of Sulprex[®] Nebuliser Solution and warned not to allow the Solution or mist to enter the eyes.

In the following conditions it should only be used after careful risk/benefit assessment: insufficiently controlled diabetes mellitus, recent myocardial infarction and/or vascular disorders, hyperthyroidism, prostatic hypertrophy or bladder-neck obstruction.

Patients with underlying severe heart disease (e.g. ischaemic heart disease, tachyarrhythmia or severe heart failure) who are receiving salbutamol for respiratory disease, should be warned to seek medical advice if they experience

chest pain or other symptoms of worsening heart disease.

Potentially serious hypokalaemia may result from beta2-agonist therapy. Particular caution is advised in concomitant treatment with xanthine derivatives, steroids and diuretics.

PREGNANCY AND LACTATION

It should not be used in pregnancy, especially the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus. Similarly, it should not be administered to breast-feeding mothers unless the expected benefit is thought to outweigh any possible risk to the neonate.

SIDE EFFECT

Common: Dry mouth.

Uncommon: Nervousness, Dizziness, Tremor, headache, Palpitations, Tachycardia, Cough, Dysphonia, Nausea.

Very rare: Arrhythmia, Atrial fibrillation, Myocardial ischaemia.

WARNING

As the product contains no preservative, a fresh ampoule should be used for each dose and the ampoule should be opened immediately before administration. Any solution left in the ampoule should be discarded.

Do not store above 25°C. Keep ampoule in the outer carton.

For use only under the presentation of a registered physician.

HOW SUPPLIED

Sulprex[®] Nebuliser Solution: Each box contains 10 ampoules in blister packs.

Manufactured by



SQUARE

**PHARMACEUTICALS LTD.
BANGLADESH**