LUTISONE™ Nebuliser Suspension

Fluticasone Propionate

Presentation

Lutisone™ 0.5 Nebuliser Suspension: Each 2 ml contains Fluticasone Propionate BP 0.5 mg.
Lutisone™ 2 Nebuliser Suspension: Each 2 ml contains Fluticasone Propionate BP 2 mg.

Description

Fluticasone Propionate Nebuliser Suspension 0.5mg/2mL and 2mg/2mL contain an aqueous white, opaque suspension of micronised Fluticasone Propionate in an istotonic phosphate buffer (polysorbate 20, sodium chloride, sodium phosphate – dibasic anhydrous, sodium phosphate – monobasic, sorbitan monolaurate and water for injection).

Indications & Uses

Adults and adolescents over 16 years of age:
Prophylactic management in severe asthma (patients requiring high dose inhaled or oral corticosteroid therapy).
Children and adolescents from 4 to 16 years of age:
Treatment of mild to moderate acute exacerbations of asthma.

Dosage & Administration

Adults and adolescents over 16 years (prophylactic management in severe asthma):
0.5-2 mg twice daily. The recommended initial dose is 2mg twice daily. The dosage should then be adjusted until control is achieved or reduced to the minimum effective dose according to the individual response.
Children and adolescents 4 to 16 years of age (treatment of acute exacerbations of asthma):
1mg twice daily.

Side Effects

Candidiasis of the mouth and throat and/or hoarseness is commonly reported. Patients may find it helpful to rinse out their mouth with water after inhalation. As with other inhalation therapy, paradoxical bronchospasm may occur rarely, with an immediate increase in wheezing after dosing. There have also been rare reports of hypersensitivity reactions manifesting as angioedema, bronchospasm and very rarely, anaphylactic reactions. Other adverse events that may occur rarely include depression of plasma cortisol in adult patients on higher doses, bone density reduction, growth retardation, cataract, glaucoma.

Precautions

Fluticasone Propionate Nebuliser Suspension should not be used for the treatment of severe acute exacerbations of asthma in children and adolescents as efficacy in this situation has not been established. Patients receiving treatment with nebulised Fluticasone Propionate must be warned that if their clinical condition deteriorates, or if a dose fails to give the usual relief, they should not increase the dose or the frequency of administration, but should seek medical advice. Prolonged therapy with inhaled Fluticasone Propionate Nebuliser Suspension should be reduced gradually and not stopped abruptly, and this should be done under medical supervision.

Use in Pregnancy & Lactation

Use in Pregnancy: (Category B3)
There is inadequate evidence of safety of Fluticasone Propionate in human pregnancy. However, as with other drugs the administration of Fluticasone Propionate during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.
Use in Lactation:
The excretion of Fluticasone Propionate into human breast milk has not been investigated.

Contraindications

Fluticasone Propionate Nebuliser Suspension is contraindicated in patients with a history of hypersensitivity to any component of the preparation.

Drug interactions

Clinically significant drug interactions mediated by Fluticasone Propionate are unlikely.

Overdose

Acute inhalation of Fluticasone Propionate doses in excess of those recommended may lead to temporary suppression of adrenal function. This does not need emergency action as adrenal function is recovered in a few days, and can be verified by plasma cortisol measurements. However, if higher than recommended dosage is continued over prolonged periods, some degree of adrenal suppression may result. Monitoring of adrenal reserve may be necessary. In cases of Fluticasone Propionate overdose, therapy may still be continued at a suitable dosage for symptom control.

Storage

- Store below 30°C.
- Protect from frost and light. Do not freeze. Store upright.
- Once ampoules have been removed from their pack, they should be protected from light and used within 28 days.
- Opened ampoules should be refrigerated and used within 12 hours of opening.

Commercial Pack

Lutisone™ 0.5 Nebuliser Suspension: Each box contains 5 ampoules of 2 ml.
Lutisone™ 2 Nebuliser Suspension: Each box contains 5 ampoules of 2 ml.

Manufactured by
Incepta Pharmaceuticals Ltd
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V.N.01

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