

Lutisone[®] Nasal Spray

Fluticasone Propionate BP

Presentation

Lutisone[®] Nasal Spray: After initial priming, each actuation delivers 50 micrograms of Fluticasone Propionate BP in 100 mg of formulation through the nasal adapter.

Description

Lutisone (Fluticasone Propionate) is a synthetic, trifluorinated corticosteroid with anti-inflammatory activity. It is an aqueous suspension of microfine Fluticasone Propionate for topical administration to the nasal mucosa by means of a metering, atomizing spray pump. It is necessary to prime the pump before first use or after a period of non-use (1 week or more). Each bottle of Lutisone nasal spray provides 120 metered sprays. After 120 metered sprays, the amount of Fluticasone Propionate delivered per actuation may not be consistent and the unit should be discarded.

Indications

- Lutisone (Fluticasone Propionate) nasal spray is indicated for the management of the nasal symptoms of seasonal and perennial allergic and nonallergic rhinitis in adults and pediatric patients 4 years of age and older.
- Prevention of recurrence of nasal polyps following surgical removal.

Dosage and Administration

Adults & Children over 12 years: 2 sprays in each nostril once a day, preferably in the morning. In some cases 2 sprays into each nostril twice daily, not exceeding 4 sprays.

Children under 12 years (4 - 11 Years): 1 spray in each nostril once a day. The maximum total daily dosage should not exceed 4 sprays.

Patients should use Lutisone (Fluticasone Propionate) nasal spray at regular intervals as directed since its effectiveness depends on its regular use.

Side effects

Fluticasone Propionate nasal spray is absorbed less into the rest of the body, therefore fewer side effects are seen. With the nasal spray, drying of the nose and an increase in the incidence of nosebleeds may occur.

Contraindications

Fluticasone Propionate nasal spray is contraindicated in patients with a hypersensitivity to any of its ingredients.

Precautions

Rarely, immediate hypersensitivity reactions or contact dermatitis may occur after the administration of Fluticasone Propionate nasal spray. Rare instances of wheezing, nasal septum perforation, cataracts, glaucoma and increased intraocular pressure have been reported following the intranasal application of corticosteroids, including Fluticasone Propionate. Although systemic effects have been minimal with recommended doses of Fluticasone Propionate nasal spray, potential risk increases with larger doses. Therefore, larger than recommended doses of Fluticasone Propionate nasal spray should be avoided.

Use in pregnancy and lactation

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Fluticasone Propionate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known whether Fluticasone Propionate is excreted in human breast milk. Because other corticosteroids are excreted in human milk, caution should be exercised when Fluticasone Propionate nasal spray is administered to a nursing woman.

Pediatric use

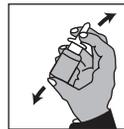
The safety and effectiveness of Fluticasone Propionate nasal spray in children below 4 years of age have not been established.

Pharmaceutical precaution

- Store at a temperature not exceeding 30°C.
- Protect from light and moisture.
- Keep out of the reach of children.

How to use the Nasal Spray

1. Shake the bottle gently and remove the dust cover.



2. Hold the spray with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle. If using for the first time or if you have not used it for a week or more, press the nasal applicator several times until a fine mist comes out from the container.



3. Gently blow the nose to clear the nostrils.



4. Close one nostril and carefully insert the nasal applicator into the open nostril. Tilt your head forward slightly and keep the spray upright. Breathe in through your nose and while breathing in, press the white collar of nasal applicator firmly down once to release a spray.



5. Breathe out through your mouth.



6. Repeat the above steps in the same/other nostril for consecutive doses.



Cleaning

The nasal spray should be cleaned at least once a week. The procedures are as follows -

- Remove the dust cover.
- Gently pull off the nasal applicator.
- Wash the applicator and dust cover in warm water.
- Shake off the excess water and leave to dry in a normal place. Avoid to apply additional heat.
- Gently push the applicator back on the top of the bottle and re-fix the dust cover.

Package quantities

Lutisone[®] Nasal Spray is supplied in amber glass bottle fitted with a metering atomizing pump, nasal applicator and dust cover. Each bottle provides Fluticasone Propionate aqueous suspension adequate for 120 metered doses.

Manufactured by
 **Incepta Pharmaceuticals Ltd**
Savar, Dhaka, Bangladesh

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