

COMPOSITION

Each actuation delivers Fluticasone Furoate INN 27.5 microgram.

PHARMACOLOGY

Fluticasone Furoate is a synthetic trifluorinated corticosteroid with potent anti-inflammatory activity. Like other corticosteroids, Fluticasone Furoate is found to have a wide range of actions on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation. Intranasal administration of Fluticasone Furoate significantly improves nasal symptoms (comprising rhinorrhoea, nasal congestion, sneezing and nasal itching) and ocular symptoms (comprising itching/burning, tearing/watering and redness of the eyes). Efficacy is maintained over the full 24-hours dosing period with once daily administration.

INDICATION

Avamist (Fluticasone Furoate) nasal spray is indicated for the treatment of the symptoms of seasonal and perennial allergic rhinitis in adults & children aged 2 years and older.

DOSAGE & ADMINISTRATION

Avamist nasal spray is recommended for intranasal use only.

Adults and adolescents aged 12 years and older: The recommended starting dose is 2 sprays in each nostril once daily. When maximum benefit is achieved with controlled symptoms then only 1 spray in each nostril once daily may be used to reduce possible side effects.

Children aged 2 to 11 years: The recommended starting dose is 1 spray in each nostril once daily.

How to Use: Prime **Avamist** nasal spray before using for the first time by shaking the contents well and releasing 6 sprays into the air away from the face. When **Avamist** nasal spray has not been used for more than 30 days or if the cap has been left off the bottle for 5 days or longer, prime the pump again until a fine mist appears.

Step 01: Shake the bottle gently



Step 02: Remove the dust cap and neck lock



Step 03: During application, tilt your head slightly forward and keep the container upright then use the nasal spray



Step 04: After each use, gently wipe the spray tip with clean & soft cloth or tissue paper. Finally set the dust cap in the previous place



CONTRA-INDICATION

It is contraindicated in patients with hypersensitivity to Fluticasone Furoate or any of its ingredients.

WARNING AND PRECAUTION

Rare incidence of nasal septum perforation, cataracts, glaucoma and impaired wound healing has been reported following the intranasal application of Fluticasone Furoate. Monitor patients closely with a change in vision or with a history of increased intraocular pressure, glaucoma or cataract, tuberculosis, ocular herpes simplex, chickenpox and measles and also for signs of adverse effects on the nasal mucosa. Avoid use in patients with recent nasal ulcers, nasal surgery, or nasal trauma. Use **Avamist** nasal spray with caution in patients with severe hepatic impairment.

SIDE EFFECTS

As Fluticasone Furoate nasal spray is less absorbed in the rest of the body, it results in fewer side effects. Most common side effects are headache, epistaxis, *Candida albicans* infection, pharyngolaryngeal pain, nasal ulceration, back pain, pyrexia and cough.

USE IN PREGNANCY & LACTATION

There are no adequate and well-controlled studies in pregnant women. **Avamist** nasal spray should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Fluticasone Furoate is excreted in human breast milk. However, other corticosteroids have been detected in human milk. So caution should be exercised when Fluticasone Furoate nasal spray is administered to a nursing woman.

USE IN CHILDREN AND ADOLESCENTS

The safety and effectiveness of **Avamist** nasal spray in children younger than 2 years have not been established. Controlled clinical trials have shown that intranasal corticosteroids may cause a reduction in growth velocity in paediatric patients. The potential for Fluticasone Furoate to cause growth suppression in susceptible patients or when given at higher than recommended dosages cannot be ruled out.

DRUG INTERACTION

Potent inhibitors of cytochrome P450 3A4 (CYP3A4) may increase exposure to Fluticasone Furoate. Coadministration of Ritonavir is not recommended. Use caution with coadministration of other potent CYP3A4 inhibitors, such as Ketoconazole.

OVERDOSE

Chronic overdoses may result in signs/symptoms of hypercorticism. There are no data on the effects of acute or chronic overdoses with **Avamist** nasal spray. Because of low systemic bioavailability and an absence of acute drug-related systemic findings in clinical studies [with doses up to 440 mcg/day for 2 weeks (4 times the maximum recommended daily doses)], overdose is unlikely to require any therapy other than observation.

STORAGE CONDITION

Keep below 30° C temperature in a dry place, protected from light. Do not refrigerate or freeze. Keep out of the reach of children.

PACKING

Each bottle contains Fluticasone Furoate suspension for 120 metered sprays.