

Flutica

Nasal Spray

Fluticasone Furoate INN
27.5 mcg/spray

Composition:

Flutica Nasal Spray: Each metered dose spray contains Fluticasone Furoate INN 27.5 mcg.

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.

Indications:

Flutica Nasal Spray is indicated for the treatment of symptoms of seasonal and perennial allergic rhinitis in adults and children above 2 years and for the prevention of recurrence of nasal polyps following surgical removal.

Dosage and administration:

For intranasal use only.

Adults and adolescents (12 years and over)

The recommended starting dosage is 2 sprays in each nostril once daily. Once adequate control of symptoms is achieved, dose reduction to one spray in each nostril once daily can be effective for maintenance.

Children (2 to 11 years of age)

The recommended starting dose is 1 spray in each nostril once daily.

Contraindications:

Fluticasone Furoate is contraindicated for the patients who have hypersensitivity to any components of this preparation.

Precautions:

Patients taking Fluticasone Furoate nasal spray should be periodically monitored for signs of adverse effects on the nasal mucosa such as epistaxis, nasal ulceration and impaired wound healing. Avoid using the drug in patients with recent nasal ulcers, nasal surgery, or nasal trauma. Closely monitor patients with a history of increased intraocular pressure, glaucoma and hypersensitivity reactions (including anaphylaxis, angioedema, rash, and urticaria). Besides, potential worsening of existing fungal, bacterial, viral, or parasitic infections or ocular herpes simplex, hypercorticism and growth retardation may occur after the administration of Fluticasone Furoate nasal spray.

Side effects:

The most common side effects are headache, epistaxis, pharyngolaryngeal pain, nasal ulceration, back pain, pyrexia, and cough.

Use in Special Groups:

Use in pregnancy: Pregnancy category C. Fluticasone Furoate nasal spray should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus.

Use in lactation: It is not known whether Fluticasone Furoate is excreted in human breast milk. Caution should be exercised when Fluticasone Furoate is administered to a nursing woman.

Geriatric use: In general, dose selection for the elderly patient should be cautious, keeping in mind the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Use in hepatic impairment: Use Fluticasone Furoate with caution in patients with severe hepatic impairment.

Use in renal impairment: No dosage adjustment is required in patients with renal impairment.

Drug interactions:

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.

Storage:

- Store below 30°C, keep in dry place & protect from light.
- Do not refrigerate or freeze.
- Keep out of the reach of children.

Packing:

Flutica Nasal Spray: Each bottle contains Fluticasone Furoate aqueous suspension for 120 metered sprays.

Special instruction:

Patients should be instructed that the device must be prepared properly:

- before first use, and
- if the cap is left off
- if the device does not seem to be working
- if the nasal spray has not been used for 30 days or more

How to prepare and use the Nasal Spray



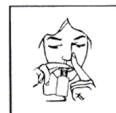
1. Shake the bottle vigorously for about 10 seconds and remove the dust cover.



2. Put 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 approximately 6 times until a fine mist comes out from the container.



3. Blow the nose gently to clear the nostrils.



4. Close one nostril with the finger. Lean head slightly forward and keeping the spray upright carefully insert the nasal applicator into the open nostril. 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.



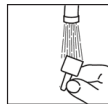
6. For consecutive doses, repeat above steps in the same/other nostril.

Cleaning

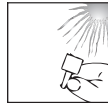
The nasal spray should be cleaned at least once a week or when the spray is blocked. Don't try to clean the nozzle with any needle. The cleaning procedures are as follows –



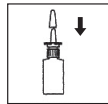
- Remove the dust cover and gently pull off the nasal applicator.



- Wash the applicator and dust cover in warm water.



- Shake off excess water and leave to dry in a normal place. Avoid applying additional heat.



- Gently push the applicator back on the top of the bottle and re-fix the dust cover.



Manufactured by:

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