

Fluticasone Furoate (27.5mcg) + Azelastine (140mcg)

Flutialfa AZ Nasal Spray

**Fluticasone Furoate (27.5mcg) + Azelastine (140mcg)
Nasal Spray**

Composition:

Each actuation delivers:

- **Fluticasone Furoate: 27.5 mcg**
- **Azelastine Hydrochloride: 140 mcg**

Pharmacological Class:

- **Fluticasone Furoate: Corticosteroid (anti-inflammatory).**
- **Azelastine Hydrochloride: Antihistamine (H1 receptor antagonist).**

Indications:

This nasal spray is indicated for:

- **Allergic Rhinitis: Seasonal and perennial.**
- **Nasal Congestion and Sneezing: Associated with allergies.**
- **Itchy or Runny Nose: Due to allergic reactions.**

Mechanism of Action:

- **Fluticasone Furoate: Reduces nasal inflammation by inhibiting the release of inflammatory mediators.**
- **Azelastine Hydrochloride: Blocks histamine receptors, reducing allergic symptoms such as itching, sneezing, and runny nose.**

Dosage and Administration:

- **Adults and Adolescents (12 years and older): 1 spray in each nostril twice daily (morning and evening).**
- **Children (6 to 11 years): 1 spray in each nostril once daily, or as directed by a healthcare provider.**

Instructions for Use:

1. **Shake the bottle gently before use.**
2. **Remove the protective cap.**

3. **Prime the spray by pumping until a fine mist appears (if using for the first time or after a long period of non-use).**
4. **Tilt the head slightly forward and insert the nozzle into one nostril.**
5. **Press the pump while breathing in gently through the nose.**
6. **Repeat for the other nostril.**
7. **Wipe the nozzle and replace the cap after use.**

Contraindications:

- **Hypersensitivity to fluticasone, azelastine, or any excipients in the formulation.**
- **Use in patients with untreated fungal, bacterial, or viral infections of the nasal passages.**

Warnings and Precautions:

- **Local Nasal Effects: Risk of nasal septal perforation or ulceration; monitor for symptoms like persistent nasal discomfort.**
- **Systemic Effects: May cause suppression of the hypothalamic-pituitary-adrenal (HPA) axis with prolonged use.**
- **Growth Suppression: Monitor growth in pediatric patients during prolonged therapy.**
- **Glaucoma and Cataracts: Use cautiously in patients with a history of ocular conditions; regular monitoring is recommended.**
- **Infections: Corticosteroids may mask signs of infection.**

Side Effects:

- **Common Side Effects:**
 - Nasal irritation or dryness
 - Bitter taste
 - Headache
 - Sneezing
- **Serious Side Effects:**
 - Epistaxis (nosebleed)
 - Hypersensitivity reactions (rash, swelling, difficulty breathing)
 - Visual disturbances

Drug Interactions:

- **Ritonavir and Ketoconazole:** May increase systemic exposure to fluticasone, leading to adrenal suppression.
- **CNS Depressants:** Additive sedative effects with azelastine; avoid alcohol.

Storage:

- Store at a temperature between 15°C to 25°C.
- Protect from light and moisture.
- Keep out of reach of children.

Packaging:

- Available in a metered-dose nasal spray bottle.
- Each bottle delivers [X] actuations.

Manufacturer:

- [Manufacturer Name]

Note:

- For intranasal use only; do not spray into the eyes or mouth.
- Consult a healthcare provider if symptoms persist or worsen after 7 days.
- Do not use for more than the prescribed duration without medical advice.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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