

Information For the Use
Fluticasone Propionate (0.005% w/v)

Flutialfa™ Nasal Spray

Fluticasone Propionate (0.005% w/v) Nasal Spray

Category:
Corticosteroid Nasal Spray

Dosage Form:
Nasal Spray

Strength:

- Fluticasone Propionate (0.005% w/v)

Description:

Fluticasone Propionate Nasal Spray is a corticosteroid used for the treatment of nasal allergy symptoms, such as congestion, sneezing, runny nose, and itchy nose caused by allergic rhinitis. It works by reducing inflammation in the nasal passages to relieve symptoms associated with allergic reactions. This nasal spray formulation offers local action with minimal systemic absorption, making it effective and generally well-tolerated.

Composition (per spray):

- Fluticasone Propionate: 0.005% w/v

Other ingredients:

- Sodium chloride
- Citric acid
- Disodium edetate
- Benzalkonium chloride
- Purified water

Indications:

- Allergic Rhinitis:
 - Seasonal Allergic Rhinitis (hay fever).
 - Perennial Allergic Rhinitis (year-round allergies).
- Nasal Congestion:
 - Reduces nasal congestion and inflammation caused by allergies.
- Preventive Treatment:
 - Used for prevention and treatment of allergic rhinitis symptoms, such as sneezing, nasal itching, and runny nose.

Mechanism of Action:

Fluticasone Propionate is a synthetic corticosteroid that works by binding to glucocorticoid receptors in the nasal mucosa, which results in the inhibition of pro-inflammatory mediators such as cytokines and chemokines. This leads to a reduction in nasal inflammation, swelling, and mucus production, providing relief from nasal allergy symptoms.

Dosage and Administration:

- Adults and Children (12 years and older):
 - Initial Dose: 1 spray (50 mcg) per nostril once daily (total of 200 mcg daily).
 - Maintenance Dose: 1 spray (50 mcg) per nostril once daily (total of 200 mcg daily). For some patients, the dose can be reduced to 1 spray (50 mcg) per nostril every other day once symptoms are controlled.
 - Maximum Dose: 2 sprays per nostril once daily (total of 400 mcg daily) for severe symptoms.
- Children (4–11 years old):
 - Initial Dose: 1 spray (50 mcg) per nostril once daily (total of 100 mcg daily).
 - Maintenance Dose: 1 spray (50 mcg) per nostril once daily (total of 100 mcg daily).

Instructions for Use:

1. Shake the nasal spray bottle gently before use.
2. Blow your nose gently to clear the nostrils.
3. Insert the spray tip into one nostril and close the other nostril by pressing it with a finger.
4. Spray once while inhaling gently through the nostril. Repeat for the other nostril.
5. After use, clean the spray nozzle with a clean tissue or cloth.

Note: It may take several days of use to notice the full effect. For best results, use the nasal spray regularly, even when symptoms are not present.

Contraindications:

- Hypersensitivity: Contraindicated in patients with known hypersensitivity to fluticasone propionate or any component of the formulation.

- Active Nasal Infections: Should not be used in the presence of untreated fungal, bacterial, viral, or parasitic infections of the nasal mucosa.

Precautions:

- Nasal Septum Perforation: Use with caution in patients with a history of nasal septum perforation.
- Immunosuppression: Corticosteroids like fluticasone may suppress the immune system. Caution is advised for patients with infections or those who have recently had exposure to infections.
- Children: Use in children should be supervised. Long-term use in children should be monitored for potential growth suppression.
- Pregnancy and Lactation: Should be used during pregnancy only if clearly needed. Consult a healthcare provider before using during pregnancy or breastfeeding.
- Systemic Absorption: Although systemic absorption is minimal, caution should be exercised in patients with a history of glaucoma or cataracts.

Adverse Effects:

Common side effects may include:

- Nasal irritation or dryness
- Sneezing
- Nosebleeds (epistaxis)
- Throat irritation
- Headache
- Cough

Serious side effects (less common but may occur):

- Vision problems (blurred vision, cataracts, or glaucoma)
- Severe allergic reactions (rash, itching, swelling, difficulty breathing)
- Nasal septum perforation (rare)

Drug Interactions:

- Other Nasal Steroids: Using multiple nasal steroid products concurrently may increase the risk of side effects.
- CYP3A4 Inhibitors: Fluticasone is metabolized by CYP3A4, so drugs that inhibit this enzyme (e.g., ritonavir, ketoconazole) may increase fluticasone plasma levels, enhancing systemic side effects.

Storage Instructions:

- Store at room temperature (15°C to 30°C).

- Do not freeze.

- Keep the spray bottle tightly closed when not in use.

- Keep out of the reach of children.

Key Benefits:

- Reduces Inflammation: Provides relief from nasal congestion, sneezing, itching, and runny nose caused by allergic rhinitis.
- Long-lasting Relief: Once-daily use provides sustained symptom control throughout the day.
- Minimal Systemic Absorption: Local action in the nasal passage with minimal systemic side effects.

Note:

Fluticasone propionate nasal spray should be used regularly for optimal symptom relief. If symptoms persist or worsen, it is important to consult a healthcare provider to reassess the treatment plan.

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