

Composition:

Each actuation contains:

Fluticasone propionate 50 µg

Properties:

Fluticasone propionate is a synthetic corticosteroid with anti-inflammatory activity. It reduces the number of mediator cells in the nasal mucosa, nasal reactivity to allergens, and release of inflammatory mediators and proteolytic enzymes. The therapeutic effects of fluticasone propionate are thought to result from local actions of the deposited inhaled dose on the nasal mucosa rather than from the systemic actions of the swallowed portion of the dose. Following topical application to the nasal mucosa, fluticasone propionate produces anti-inflammatory and vasoconstrictor effect. Patients receiving short- and long-term treatment with intranasal fluticasone propionate have demonstrated decreases in nasal turbinate swelling and mucosal inflammation.

Indications:

TICANASE is an aqueous Nasal Spray indicated for the management of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and pediatric patients 4 years of age and older.

Dosage:

- Shake the bottle before use.

- Patients should use **TICANASE** Nasal Spray at regular intervals as directed since its effectiveness depends on its regular use.

Adults: The recommended starting dosage in adults is two sprays in each nostril once-a-day (total daily dose, 200 µg). The same dosage divided into 100 µg twice daily is also effective.

After the first few days, patients may be able to reduce their dosage to 100 µg (one spray in each nostril) once daily for maintenance therapy.

Adolescents and Children (4 years of age and older): Patients should be started with 100 µg (one spray in each nostril once-a-day). Patients not adequately responding to 100 µg may use 200 µg (two sprays in each nostril). Once adequate control is achieved, the dosage should be decreased to 100 µg (one spray in each nostril) daily. The maximum total daily dose should not exceed two sprays in each nostril (200 µg per day).

Adverse reactions:

General: Hypersensitivity reactions, including angioedema, skin rash, edema of the face and tongue, pruritus, urticaria, bronchospasm, wheezing, dyspnea, and anaphylaxis/anaphylactoid reactions, which in rare instances were severe.

Ear, nose, and throat: Alteration or loss of sense of taste and/or smell and extremely rare nasal septal perforation, nasal ulcer, sore throat, throat irritation and dryness, cough, hoarseness and voice changes.

Eye: Dryness and irritation, conjunctivitis, blurred vision, glaucoma, increased intraocular pressure, and cataracts.

Precautions:

- Although systemic effects have been minimal with recommended doses of fluticasone, overdosage of **TICANASE** Nasal Spray should be avoided.

- If localized infections of the nose and pharynx with *Candida albicans* have occurred, treatment with appropriate local therapy is needed and discontinue the treatment with **TICANASE** Nasal Spray.

- Patients using **TICANASE** Nasal Spray over several months or longer should be examined periodically for evidence of *Candida* infection or other signs of adverse effects on the nasal mucosa.

- **TICANASE** Nasal Spray should be used with caution, if at all, in patients with active or quiescent tuberculous infection; untreated local or systemic fungal or bacterial, or systemic viral infections or parasitic infection, or ocular herpes simplex.

- Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal septal ulcers, nasal surgery, or nasal trauma should not use a nasal corticosteroid until healing has occurred.

- Pregnancy and lactation: **TICANASE** Nasal Spray should be used during pregnancy or lactation only if the potential benefit justifies the potential risk to the fetus.

Contraindications:

- Hypersensitivity to any of its ingredients.

- The safety and effectiveness of fluticasone in children under 4 years of age have not been established.

Presentation:

A bottle containing 12 gm (120 metered sprays) fitted with a metered atomising pump and a nasal adaptor.

