

# Avaspray™

Fluticasone Furoate INN 27.5 mcg/spray

## Metered Dose Nasal Spray

### COMPOSITION

Each metered spray delivers Fluticasone Furoate INN 27.5 mcg.

### PHARMACOLOGY

Fluticasone Furoate is a synthetic trifluorinated corticosteroid with potent anti-inflammatory activity. The precise mechanism through which Fluticasone Furoate affects rhinitis symptoms is not known. Corticosteroids have been shown to have a wide range of actions on multiple cell types (e.g. mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g. histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation. These anti-inflammatory actions of corticosteroids may contribute to their efficacy in rhinitis.

Following intranasal administration of Fluticasone Furoate most of the dose is eventually swallowed and undergoes incomplete absorption and extensive first-pass metabolism in the liver and gut, resulting in negligible systemic exposure. The plasma protein binding of Fluticasone Furoate is greater than 99%. Fluticasone Furoate and its metabolites are excreted through the bile.

### INDICATION

Avaspray Nasal Spray is indicated for the treatment of the symptoms of seasonal and perennial allergic rhinitis in patients above 2 years of age.

### DOSAGE AND ADMINISTRATION

For adults and adolescents 12 years of age and older the recommended dosage is two sprays in each nostril once daily.

For patients 2 to 12 years of age the recommended starting dosage is one spray in each nostril once daily. Patients not adequately responding to one spray in each nostril once daily may use two sprays in each nostril once daily. Once adequate control of symptoms is achieved, dose reduction to one spray in each nostril once daily is recommended.

### PRECAUTIONS

Co-administration with ritonavir is not recommended because of the risk of systemic effects secondary to increased exposure to Fluticasone Furoate. When intranasal steroids are used at higher than recommended dosages or in susceptible individuals at recommended dosages, systemic corticosteroid effects such as hypercorticism and suppression of HPA function may occur. As with all medications containing a corticosteroid, Fluticasone Furoate nasal spray should be administered with caution and only if necessary, in patients with active or quiescent tuberculosis infections of the respiratory tract; chronic or untreated infections such as systemic fungal, bacterial, viral, or parasitic; or ocular herpes simplex.

### SIDE EFFECTS

The most common adverse reactions included headache, epistaxis, pharyngolaryngeal pain, nasal ulceration, back pain, nasopharyngitis, upper respiratory tract infection, nausea, and cough.

### USE IN PREGNANCY

Pregnancy Category: C.

Fluticasone Furoate Nasal Spray should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

### STORAGE CONDITION

Store below 30°C, in the upright position with the cap in place. Do not refrigerate or freeze. Shake gently before use. Keep out of reach of children.

### HOW SUPPLIED

Each bottle contains uniform suspension of Fluticasone Furoate adequate for 120 metered sprays.

Manufactured by



**SQUARE**  
PHARMACEUTICALS LTD.  
BANGLADESH