

**Facts about:
VERAMYST™ (fluticasone furoate) Nasal Spray**

VERAMYST™ Nasal Spray is a once-daily intranasal corticosteroid (INS) indicated for the treatment of symptoms of seasonal (outdoor) and perennial (year-round indoor) allergic rhinitis in adults and children two years of age and older.

The Newest Intranasal Corticosteroid

VERAMYST treats overall nasal allergy symptoms that include congestion, sneezing, and itchy and runny nose, as demonstrated in clinical trials of more than 2,900 adults and children two years of age and older with seasonal and year-round allergies.

VERAMYST also demonstrated consistent and significant improvement in relieving overall eye symptoms, including itchy, red and watery eyes in seasonal allergy patients 12 years and older in three prospectively designed studies.

The unique, ergonomically designed device for VERAMYST has a side-actuated mist release button that, when pressed, delivers the same amount of medicine every time so patients know that they are getting the full dose that their doctor has prescribed.

Clinical Highlights

VERAMYST has been shown to be effective in the treatment of symptoms of seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR).

Adults and Adolescents

- In five pivotal, randomized, double-blind, parallel-group, multicenter, placebo-controlled clinical trials involving 1,829 adults and adolescents aged 12 years and older with symptoms of SAR or PAR:
 - ⇒ Nasal symptoms: VERAMYST was significantly better than placebo in relieving overall nasal allergy symptoms including nasal congestion, sneezing, itchy nose and runny nose in patients with SAR or PAR.
 - ⇒ Ocular symptoms: VERAMYST is the first and only INS to demonstrate consistent and significant improvement compared to placebo in relieving overall eye symptoms including itchy, red and watery eyes, in three prospectively designed and replicated clinical trials in 886 SAR patients 12 years of age and older.
 - Improvement in eye symptoms was not shown in PAR patients.
 - ⇒ 24-Hour Relief: The improvement of nasal symptoms with VERAMYST lasted for a full 24 hours in SAR patients.
 - ⇒ Quality of Life: Adult and adolescent patients with seasonal allergies 12 years of age and older taking VERAMYST reported statistically significant and clinically meaningful improvement in overall allergy-related quality of life (QOL) scores compared with placebo.

- QOL measures included the impact of treatment on activities, sleep, non-nose, non-eye symptoms, practical problems, nasal symptoms, eye symptoms and emotional problems.
- In adult and adolescent patients with PAR, improvements in overall allergy-related quality of life scores were not statistically significant compared with placebo.

Pediatric Patients

- In two pediatric studies involving 1,112 children two to 11 years of age with SAR or PAR, VERAMYST effectively treated overall nasal symptoms which included nasal congestion, sneezing, and itchy and runny nose:
 - ⇒ In SAR patients, the difference was statistically significant for the 110 mcg dose.
 - ⇒ In PAR patients, the difference was statistically significant for the 55 mcg dose.
 - ⇒ Improvement in eye symptoms was not shown in SAR patients and was not assessed in PAR patients.

Safety Profile

- Common adverse reactions included headache, nose bleed and nasal sores. Fever occurred more frequently in children treated with VERAMYST compared to placebo.
- In one long-term 12-month study, adverse reactions were similar in type and rate between the VERAMYST and placebo groups. However, nose bleed occurred more frequently in the group receiving VERAMYST (20%) than in the placebo group (8%). The episodes of nose bleed were of mild intensity in the majority of patients (17/17 in the placebo group and 83/123 in the group receiving VERAMYST). The episodes were of moderate intensity in 39 patients and of severe intensity in one patient receiving VERAMYST.

Unique Delivery System

- VERAMYST is delivered in a unique, ergonomically designed device that was developed to address patients' common concerns. Key features include:
 - ⇒ A side-actuated mist release button that, when pressed, delivers the same amount of medicine each time
 - ⇒ A viewing window that allows patients to see how much medicine is left in the bottle
 - ⇒ A gentle, scent-free mist with a low volume of spray

Dosage

The recommended starting dose is 110 mcg (two mists per nostril) once daily for patients 12 years of age and older. When symptoms have been controlled the dosage may be reduced to 55 mcg (one mist in each nostril once daily).

The recommended starting dose is 55 mcg (one mist per nostril) once daily for children two to 11 years of age. Children not adequately responding to 55 mcg may use 110 mcg once daily. Once symptoms have been controlled, the dosage may be decreased to 55 mcg once-daily..

*Please consult the enclosed complete Prescribing Information
for VERAMYST Nasal Spray for more information.*

#