Avamys Provides Effective Relief from the Cardinal Symptoms of AR†[1,2]

Avamys moments

Sneezing[1]
(p<0.00001)

Nasal Itching[1]
(p<0.001)

Nasal Congestion[1]
(p<0.001)

Rhinorrhoea[1]
(p<0.001)

Mean change from baseline in daily individual nasal symptoms scores.[1]

Overall, 56% of AR† Patients Preferred FFNS* vs 32% Preferring MFNS^[3] *(p<0.001)*

Less Drip Down Nose[3]
(p<0.05)

Less Drip Down Throat[3]
(p<0.001)

More Soothing[3]
(p<0.05)

Less Irritating[3]
(p<0.001)

†AR: Allergic Rhinitis; ***FFNS:** Fluticasone Furoate Nasal Spray; **^MFNS:** Mometasone Furoate Nasal Spray.

References:

1. Vasar M, et al. Allergy Asthma Proc 2008;29(3):313–321.
2. Kakli HA, Riley TD. Prim Care 2016;43(3):465–475.
3. Yanez A, et al. A patient preference study that evaluated fluticasone furoate and mometasone furoate nasal sprays for allergic rhinitis. Allergy Rhinol 2016; 7(4):e183–e192.

ABBREVIATED PRESCRIBING INFORMATION FOR Avamys Nasal Spray

Product Name and Active Ingredient: Avamys Nasal Spray: *AVAMYS* Nasal Spray is a white, uniform suspension contained in an amber glass bottle, fitted with a metering (50 microlitres) atomising spray pump. Each spray of the suspension delivers approximately 27.5 micrograms of micronised fluticasone furoate as an ex-device dose. **Indications: Adults and Adolescents (12 years and older):** Treatment of the nasal symptoms (rhinorrhea, nasal congestion, nasal itching and sneezing) and ocular symptoms (itching/burning, tearing/watering, and redness of the eye) of seasonal allergic rhinitis. Treatment of the nasal symptoms (rhinorrhea, nasal congestion, nasal itching and sneezing) of perennial allergic rhinitis. **Children (2 to 11 years):** Treatment of the nasal symptoms (rhinorrhea, nasal congestion, nasal itching and sneezing) of seasonal and perennial allergic rhinitis. **Dosage and Administration:** *AVAMYS* Nasal Spray is for administration by the intranasal route only. For full therapeutic benefit regular scheduled usage is recommended. Onset of action has been observed as early as 8 hours after initial administration. It may take several days of treatment to achieve maximum benefit. An absence of an immediate effect should be explained to the patient. **Populations:** For the treatment of seasonal allergic rhinitis and perennial allergic rhinitis: **Adults and Adolescents (12 years and older):** The recommended starting dosage is 2 sprays (27.5 micrograms per spray) in each nostril once daily (total daily dose, 110 micrograms). Once adequate control of symptoms is achieved, dose reduction to 1 spray in each nostril once daily (total daily dose, 55 micrograms) may be effective for maintenance. **Children (2 to 11 years):** The recommended starting dosage is 1 spray (27.5 micrograms per spray) in each nostril once daily (total daily dose, 55 micrograms). Patients not adequately responding to one spray in each nostril once daily (total daily dose, 55 micrograms) may use 2 sprays in each nostril once daily (total daily dose, 110 micrograms). Once adequate control of symptoms is achieved, dose reduction to 1 spray in each nostril once daily (total daily dose, 55 micrograms) is recommended. **Children (under 2 years of age):** There are no data to recommend use of *AVAMYS* Nasal Spray for the treatment of seasonal or perennial allergic rhinitis in children under 2 years of age. **Elderly:** No dosage adjustment required. **Renal impairment:** No dosage adjustment required. **Hepatic impairment:** No dosage adjustment is required in patients with hepatic impairment. **Contraindications:** *AVAMYS* Nasal Spray is contra-indicated in patients with hypersensitivity to any of the ingredients. **Pregnancy:** Following intranasal administration of *AVAMYS* Nasal Spray at the maximum recommended human dose (110 micrograms/day), plasma fluticasone furoate concentrations were typically non-quantifiable and therefore potential for reproductive toxicity is expected to be very low. **Lactation:** The excretion of fluticasone furoate into human breast milk has not been investigated. **Warnings and Precautions:** Based on data with another glucocorticoid metabolised by CYP3A4, co-administration with ritonavir is not recommended because of the potential risk of increased systemic exposure to fluticasone furoate. Systemic effects with nasal corticosteroids have been reported, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. A reduction in growth velocity has been observed in children treated with fluticasone furoate 110 micrograms daily for one year (see Adverse Reactions). Therefore, children should be maintained on the lowest dose which delivers adequate symptom control (see Dosage and Administration). As with other intranasal corticosteroids, physicians should be alert to potential systemic steroid effects including ocular changes such as central serous chorioretinopathy. **Adverse Reactions:** Data from large clinical trials were used to determine the frequency of adverse reactions. The following convention has been used for the classification of frequency: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000). **Clinical Trial Data:** Respiratory, thoracic and mediastinal disorders. Very common: Epistaxis. In adults and adolescents, the incidence of epistaxis was higher in longer-term use (more than 6 weeks) than in short-term use (up to 6 weeks). In paediatric clinical studies of up to 12 weeks duration the incidence of epistaxis was similar between *AVAMYS* Nasal Spray and placebo. Common: Nasal ulceration. **Children:** Musculoskeletal and connective tissue disorders. Not known: Growth retardation. In a one-year clinical study assessing growth in pre-pubescent children receiving 110 micrograms of fluticasone furoate once daily, an average treatment difference of -0.27 cm per year in growth velocity was observed compared to placebo (see Clinical Studies). **Post-Marketing Data:** Immune system disorders. Rare: Hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria. **Nervous system disorders:** Common: Headache. Respiratory, thoracic and mediastinal disorders. Uncommon: Rhinalgia, nasal discomfort (including nasal burning, nasal irritation and nasal soreness), nasal dryness. Very rare: Nasal septum perforation. Please read the full prescribing information prior to administration, available from: GlaxoSmithKline Pharmaceutical Sdn Bhd (3277-U) Level 6, Quill 9, 112 Jalan Semangat, 46300 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

Abbreviated Prescribing Information Version 03 based on GDS11/IPI10.

Date of revision: 24th January 2019.

For Medical/Healthcare Professionals Only.

Prescribing Information: Before prescribing, please refer to the full Avamys Nasal Spray (Fluticasone Furoate Nasal Spray) prescribing information, which is available on site: https://gskpro.com/content/dam/global/hcpportal/en_MY/protected/products/avamys/pdf/Avamys_v03.pdf

Adverse events should be reported to drugsafetyinfo.my@gsk.com.

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Avamys
Fluticasone furoate

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