Avamys Prescribing Information

(Please refer to the full Summary of Product Characteristics before prescribing)

Avamys® Nasal Spray Suspension (fluticasone furoate 27.5 micrograms/metered spray)

Uses: Treatment of symptoms of allergic rhinitis in adults, adolescents and children aged 6 years and over. **Dosage and Administration:** For intranasal use only. *Adults and adolescents (12 years and older):* Two sprays per nostril once daily (total daily dose, 110 micrograms). Once symptoms controlled, use maintenance dose of one spray per nostril once daily (total daily dose, 55 micrograms). Reduce to lowest dose at which effective control of symptoms is maintained. *Children aged 6 to 11 years:* One spray per nostril once daily (total daily dose, 55 micrograms). If patient is not adequately responding, increase daily dose to 110 micrograms (two sprays per nostril, once daily) and reduce back down to 55 micrograms daily dose once control is achieved. The duration of treatment should be restricted to the period that corresponds to allergenic exposure. **Contraindications:** Hypersensitivity to active substance or excipients. **Special warnings and precautions:** Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses 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. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). If a patient presents with blurred vision or other visual disturbance, consider referral to an ophthalmologist for evaluation. Causes may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Treatment with higher than recommended doses of nasal corticosteroids may result in clinically significant adrenal suppression. If there is evidence for higher than recommended doses being used, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. It is recommended that growth of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. Aim to reduce to the lowest effective dose and consider referring to a paediatric specialist. Due to risk of increased systemic exposure, caution is advised when prescribing concurrently with other corticosteroids. **Drug interactions:** Caution is recommended when co-administering fluticasone furoate with potent CYP3A4 inhibitors (e.g. ketoconazole) including cobicistat-containing products as an increase in the risk of systemic side effects is expected. Co-administration with ritonavir is not recommended because of the risk of increased systemic exposure of fluticasone furoate. Co-administration should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side effects, in which case patients should be monitored for systemic corticosteroid side effects. **Pregnancy lactation and fertility:** No adequate data available. Recommended nasal doses result in minimal systemic exposure. It is unknown if fluticasone furoate nasal spray is excreted in breast milk. Only use during pregnancy or in breastfeeding women if the expected benefits to the mother outweigh the possible risks to the foetus or child. No fertility data in humans. **Undesirable effects:** *Very common (≥1/10):* epistaxis. Epistaxis was generally mild to moderate, with incidences in adults and adolescents higher in longer-term use (more than 6 weeks). *Common (≥1/100 and <1/10):* headache, nasal ulceration. *Uncommon (≥1/1000 and <1/100):* rhinalgia, nasal discomfort, nasal dryness. *Rare (≥1/10,000 and <1/1000):* hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria. *Very rare (<1/10,000):* Nasal septum perforation. *Not known:* transient ocular changes – blurred vision, growth retardation. Consult the SPC in relation to other adverse reactions. **Presentation and Basic NHS cost:** Avamys Nasal Spray Suspension*:* 120 sprays: £6.44 **Marketing Authorisation Number: EU/1/07/434/001-003. Legal category:** POM. **PL holder:** Glaxo Group Ltd, 980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS. **Last date of revision:** July 2017

Further information is available from the Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone: 0800 221 441.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.