

## Flonase® Sensimist<sup>™</sup> Allergy Relief (fluticasone furoate) – Rx-to-OTC Approval

- On February 8, 2017, <u>GlaxoSmithKline Consumer Healthcare announced</u> the launch of <u>Flonase Sensimist Allergy Relief (fluticasone furoate)</u> nasal spray, as an over the counter (OTC) treatment to temporarily relieve symptoms of hay fever or other upper respiratory allergies: nasal congestion; runny nose; sneezing; itchy nose; and itchy, watery eyes (in ages 12 years and older).
  - Flonase Sensimist Allergy Relief contains 27.5 mcg/spray of fluticasone furoate.
  - Flonase Sensimist Allergy Relief should not be used in children less than 2 years of age.
- Previously, fluticasone furoate was only available by prescription as <u>Veramyst</u><sup>®</sup>. Veramyst is no longer commercially available.
- Fluticasone is also available OTC as brand (<u>Flonase<sup>®</sup> Allergy Relief</u>, <u>Children's Flonase<sup>®</sup> Allergy Relief</u>) and generic products containing 50 mcg/spray of fluticasone propionate.
  - These products share the same indications as Flonase Sensimist Allergy Relief, but are not intended for children under 4 years of age.
- Prescription <u>fluticasone propionate</u> nasal spray (50 mcg/spray) is available generically and indicated for the management of the nasal symptoms of perennial non-allergic rhinitis in adult and pediatric patients aged 4 years and older.
- Warnings for Flonase Sensimist Allergy Relief state the following:
  - Do not use: in children under 2 years of age, to treat asthma, if there is an injury or surgery to the nose that is not fully healed, or if an allergic reaction to Flonase Sensimist Allergy Relief or any of its ingredients has occurred.
  - Ask a doctor prior to use if the patient has or had glaucoma or cataracts.
  - Ask a doctor or pharmacist prior to use if the patient is taking a medication for HIV infection, a steroid medicine for asthma, allergies or a skin rash, or ketoconazole.
  - Patients should stop using Flonase Sensimist Allergy Relief and consult a doctor if he or she comes into contact with someone who has chicken pox, measles, or tuberculosis, has symptoms that do not get better within 7 days of starting Flonase Sensimist Allergy Relief or experiences new symptoms such as severe facial pain or thick nasal discharge, experiences a constant whistling sound around the nose, experiences new changes to vision, or has severe or frequent nosebleeds.

• The recommended doses of Flonase Sensimist Allergy Relief are as follows:

Patient age	Dose	Duration of time
12 years of age and older	2 sprays in each nostril once daily	Week 1
	1 – 2 sprays in each nostril once daily, as needed to treat symptoms	Week 2 – 6 months After 6 months, talk to doctor about continued use.
2 – 11 years of age	1 spray in each nostril once daily	Use for the shortest time necessary to achieve relief of symptoms.  Talk to a doctor if the child needs to use the spray for longer than 2 months a year.



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