

Nasonex[®] (mometasone furoate monohydrate) – New partial over-the-counter approval

- On March 17, 2022, <u>Perrigo announced</u> the approval of partial over-the counter (OTC) use of Merck's <u>Nasonex 24HR Allergy (mometasone furoate monohydrate)</u> 50 mcg nasal spray, to temporarily relieve symptoms of hay fever or other upper respiratory allergies including nasal congestion, sneezing, runny and itchy nose in patients 2 years of age and older.
 - Previously, Nasonex was available as a <u>generic prescription</u> product indicated for the treatment of the nasal symptoms of seasonal allergic and perennial allergic rhinitis, in adults and pediatric patients 2 years of age and older; for the relief of nasal congestion associated with seasonal allergic rhinitis, in adults and pediatric patients 2 years of age and older; for the prophylaxis of the nasal symptoms of seasonal allergic rhinitis in adult and adolescent patients 12 years and older; and for the treatment of nasal polyps in patients 18 years of age and older.
 - Nasonex will remain as prescription for the treatment of nasal polyps.
- Nasonex 24HR Allergy is only for use in the nose. The products should not be sprayed in the eyes
 or mouth.
- When using Nasonex 24HR Allergy:
 - The growth rate of some children may be slower
 - Stinging may occur for a few seconds right after use
 - The patient may start to feel relief within 12 hours and full effect after several days of regular, once a day use
 - The bottle should not be shared with anyone else as this may spread germs.
- A patient should stop use and ask a doctor if:
 - They have, or come into contact with someone who has chickenpox, measles, or tuberculosis.
 - Their symptoms do not get better within seven days of starting use or they get new symptoms such as severe facial pain or thick nasal discharge. They may have something more than allergies, such as an infection.
 - They get a constant whistling sound in their nose. This may be a sign of damage inside the nose.
 - They get an allergic reaction to the product.
 - They get new changes to their vision after starting the product.
 - They have severe or frequent nosebleeds.
- The recommended dose of Nasonex 24HR Allergy is as follows:

Patient age	Dosing frequency
12 years of age and older	2 sprays in each nostril once daily while sniffling gently
2 to 11 years of age	1 spray in each nostril once daily while sniffling gently

- Children should use Nasonex 24HR Allergy for the shortest amount of time necessary to achieve symptom relief. A child's doctor should be consulted if the child needs to use Nasonex 24HR Allergy for longer than two months a year.
- An adult should supervise children who use Nasonex 24HR Allergy.

 Perrigo plans to launch Nasonex 24HR Allergy later this year. Nasonex 24HR Allergy will be available as a nasal spray containing 120 sprays (50 mcg/per spray).
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