FLONASE SENSIMIST ALLERGY RELIEF- fluticasone furoate spray, metered
Haleon US Holdings LLC

Drug Facts

Active ingredient (in each spray)

Fluticasone furoate 27.5 mcg (glucocorticold)*

*read the Question & Answer Book

Purpose

Allergy symptom reliever

Uses

Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- nasal congestion
- runny nose
- sneezing
- itchy nose
- itchy, watery eyes (for ages 12 and older)

Warnings

Only for use in the nose. Do not spray into your eyes or mouth.

Do not use

- in children under 2 years of age
- to treat asthma
- if you have an injury or surgery to your nose that is not fully healed
- if you have ever had an allergic reaction to this product or any of the ingredients

Ask a doctor before use if you

have or had glaucoma or cataracts

Ask a doctor or pharmacist before use if you are taking

- medicine for HIV infection (such as ritonavir)
- a steroid medicine for asthma, allergies or skin rash
- ketoconazole pills (medicine for fungal infection)

When using this product

- the growth rate of some children may be slower
- stinging or sneezing may occur for a few seconds right after use
- do not share this bottle with anyone else as this may spread germs
- remember to tell your doctor about all the medicines you take, including this one

Stop use and ask a doctor if

- you have, or come into contact with someone who has, chicken pox, measles or tuberculosis
- your symptoms do not get better within 7 days of starting use or you get new symptoms such as severe facial pain or thick nasal discharge. You may have something more than allergies, such as an infection.
- you get a constant whistling sound from your nose. This may be a sign of damage inside your nose.
- you get an allergic reaction to this product. Seek medical help right away.
- you get new changes to your vision that develop after starting this product
- you have severe or frequent nosebleeds

If pregnant or breast –feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- read the Quick Start Guide for how to:
    - shake vigorously before each use
    - prime the bottle
    - use the spray
    - sniff gently after each spray
- clean the spray nozzle with a clean dry tissue
- use this product only once a day
- do not use more than directed

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER

- Week 1- use 2 sprays in each nostril once daily
- Week 2 through 6 months- use 1 or 2 sprays in each nostril once daily, as needed to treat your symptoms
- After 6 months of daily use – ask your doctor if you can keep using

CHILDREN 2 TO 11 YEARS OF AGE

- the growth rate of some children may be slower while using this product. **Children should use for the shortest amount of time necessary to achieve symptom relief. Talk to your child's doctor if your child needs to use the**

spray for longer than two months a year.
- an adult should supervise use
- use 1 spray in each nostril once daily

CHILDREN UNDER 2 YEARS OF AGE

- **do not use**

Other information

- you may start to feel relief the first day and full effect after several days of regular, once-a-day use
- store between 15° and 30°C (59° and 86°F)
- do not refrigerate or freeze
- keep this label and enclosed materials. They contain important additional information.

Inactive ingredients

benzalkonium chloride, carboxymethylcellulose sodium, dextrose anhydrous, edentate disodium, microcrystalline cellulose, polysorbate 80, purified water

Questions or comments?

call toll-free **1-844-FLONASE** (1-844-356-6273)

Principal Display Panel

NDC 0135-0616-01

CHILDREN's

FLONASE®

SENSIMIST™

ALLERGY RELIEF

GENTLE MIST • SCENT FREE • ALCOHOL FREE

Fluticasone Furoate Nasal Spray 27.5 mcg Per Spray

Allergy Symptom Reliever

(Glucocorticoid)*

Full Prescription Strength Non-Drowsy 24 Hour Relief of:

- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing

24 HOUR RELIEF

*Fluticasone furoate is a steroid medicine known as a glucocorticoid.

60 METERED SPRAYS

0.20 fl oz (5.9 mL)

Distirbuted by:

GSK Consumer Healthcare

Warren, NJ 07059

Made in Singapore

IMPORTANT – Peel here for complete Drug Facts label. Children 2-11: do not use for more than 2 months a year.

Be sure to read the Quick Start Guide and Question & Answer Book inside package

TAMPER-EVIDENT *features for your protection. The product is packaged in a sealed plastic container. The bottle is housed within a plastic dispenser that prevents direct access to the bottle. Do not use if the container or any part of the plastic dispenser, including the dispenser bottom, is damaged or broken.*

Do not use if any of these features are torn or damaged.

What problems can FLONASE® SENSIMIST™ Allergy Relief help with?

FLONASE SENSIMIST Allergy Relief helps relieve a broad range of uncomfortable symptoms like congestion and itchy eyes.

Nasal symptoms

Eye symptoms

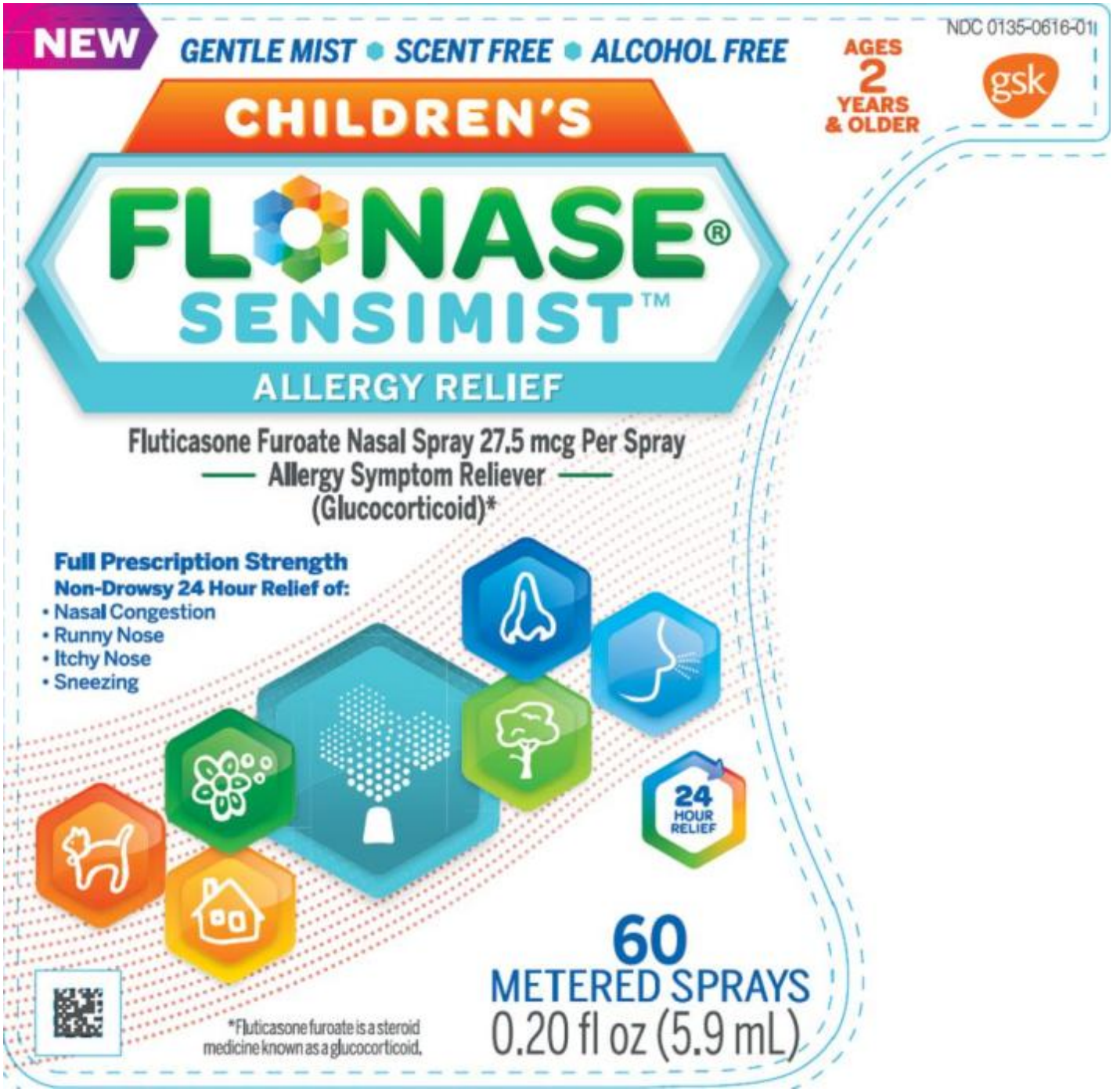
These symptoms can be triggered by allergens like pollen, mold, dust or pet dander.

Outdoor allergens

Animal allergens

Indoor allergens

Backer card: 105625XA
Peel Back Label: 105629XA



FLONASE SENSIMIST ALLERGY RELIEF

fluticasone furoate spray, metered

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0616
Route of Administration	NASAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FLUTICASONE FUROATE (UNII: JS86977WNV) (FLUTICASONE - UNII:CUT2W21N7U)	FLUTICASONE FUROATE	27.5 ug

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0616-01	1 in 1 PACKAGE	07/01/2017	
1		60 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:0135-0616-03	1 in 1 PACKAGE	07/01/2021	
2		72 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022051	07/01/2017	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 3/2024 Haleon US Holdings LLC