

**FLONASE SENSIMIST ALLERGY RELIEF- fluticasone furoate spray, metered**  
**GlaxoSmithKline Consumer Healthcare Holdings (US) LLC**

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**Drug Facts**

***Active ingredient (in each spray)***

Fluticasone furoate 27.5 mcg (glucocorticoid)\*

\*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° – 30°C (59° – 86°F)
- do not refrigerate or freeze
- keep this label and enclosed materials. They contain important additional information.

### ***Inactive ingredients***

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

### ***Questions or comments?***

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

### **Principal Display Panel**

**NDC 0135-0615-02**

**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:**

- Itchy, Watery Eyes
- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing

**24 HOUR RELIEF**

**60 METERED SPRAYS**

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

0.34 fl oz (9.9 mL)

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Distributed 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.***

**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\***

\*for ages 12 and older.

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

**Outdoor allergens**

**Animal allergens**

**Indoor allergens**

Peel Back Label: 105629XA

Blister Card Front: 105621XC

GENTLE MIST • SCENT FREE • ALCOHOL FREE

NDC 0135-0615-02



# FLONASE<sup>®</sup> SENSIMIST<sup>™</sup>

## ALLERGY RELIEF

Fluticasone Furoate Nasal Spray 27.5 mcg Per Spray  
— Allergy Symptom Reliever —  
(Glucocorticoid)\*

**Full Prescription Strength  
Non-Drowsy 24 Hour Relief of:**

- Itchy, Watery Eyes
- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing



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

**60**  
**METERED SPRAYS**  
0.20 fl oz (5.9 mL)

## FLONASE SENSIMIST ALLERGY RELIEF

fluticasone furoate spray, metered

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0615
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
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>ANHYDROUS DEXTROSE</b> (UNII: 5SL0G7R0OK)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>WATER</b> (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0615-01	1 in 1 CARTON	02/01/2017	
1		30 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:0135-0615-02	1 in 1 PACKAGE	02/01/2017	
2		60 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:0135-0615-03	1 in 1 PACKAGE	02/01/2017	
3		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:0135-0615-04	3 in 1 PACKAGE	02/01/2017	
4		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
5	NDC:0135-0615-05	2 in 1 PACKAGE	07/01/2017	
5		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
6	NDC:0135-0615-06	1 in 1 PACKAGE	01/22/2019	
6		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	02/01/2017	

**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)