

# **FLONASE SENSIMIST ALLERGY RELIEF- fluticasone furoate spray, metered A-S Medication Solutions**

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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:
  - o shake vigorously before each use
  - o prime the bottle
  - o use the spray
  - o 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)

## **HOW SUPPLIED**

Product: 50090-5967

NDC: 50090-5967-0 60 SPRAY, METERED in a BOTTLE / 1 in a PACKAGE

## **fluticasone furoate**



# FLONASE SENSIMIST ALLERGY RELIEF

fluticasone furoate spray, metered

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-5967(NDC:0135-0615)
<b>Route of Administration</b>	NASAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
FLUTICASONE FUROATE (UNII: JS86977WNV) (FLUTICASONE - UNII:CUT2W21N7U)	FLUTICASONE FUROATE	27.5 ug

## Inactive Ingredients

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

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:50090-5967-0	1 in 1 PACKAGE	04/27/2022	
1		60 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA022051	02/01/2017	

**Labeler -** A-S Medication Solutions (830016429)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
A-S Medication Solutions		830016429	RELABEL(50090-5967)

