

**FLONASE ALLERGY RELIEF- fluticasone propionate spray, metered**  
**Haleon US Holdings LLC**

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**Drug Facts**

***Active Ingredient (in each spray)***

Fluticasone propionate (glucocorticoid) 50 mcg

***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

***Warnings***

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

***Do not use***

- in children under 4 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:
  - prime the bottle
  - use the spray
  - clean the spray nozzle
- shake gently before each use
- 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 4 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 4 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 4° and 30°C (39° and 86°F)
- keep this label and enclosed materials. They contain important additional information.

### ***Inactive ingredients***

benzalkonium chloride, dextrose, microcrystalline cellulose, phenylethylalcohol, polysorbate 80, purified water, sodium carboxymethylcellulose

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

call toll-free **1-844-FLONASE**(1-844-356-6273) (English/Spanish) weekdays

### **Principal Display Panel**

**NDC 0135-0576-03**

**FLONASE®**

**ALLERGY RELIEF**

***FULL PRESCRIPTION STRENGTH \* NON-DROWSY***

**Fluticasone Propionate (Glucocorticoid) 50 mcg Per Spray**

**Allergy Symptom Reliever Nasal Spray**

#### **24 Hour Relief of:**

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

#### **24 HOUR RELIEF**

#### **120 METERED SPRAYS**

0.54 fl oz (15.8 mL)

FLONASE, the FLONASE logo, the bottle and cap design, and other design elements are trademarks of the GSK group of companies.

IMPORTANT – Peel here for complete Drug Facts label. Children 4-11: 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. Under the cap and nozzle, each bottle has an aluminum seal around bottle neck.*

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

Distributed by:

## **GlaxoSmithKline**

Consumer Healthcare, L.P.

Moon Township, PA 15108

Made in Canada

### **What problems can FLONASE<sup>®</sup> Allergy Relief help with?**

**FLONASE<sup>®</sup> 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**

- Blister card: 104447XB ©2015 GSK
- Peel Back Label: 104448XB ©2015 GSK

FULL PRESCRIPTION STRENGTH • NON-DROWSY

NDC 0135-0576-03

# FLONASE<sup>®</sup>

## ALLERGY RELIEF



Fluticasone Propionate (Glucocorticoid) 50 mcg Per Spray  
Allergy Symptom Reliever Nasal Spray

**24 Hour Relief of:**

- Itchy, Watery Eyes
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- Sneezing



**120**  
METERED SPRAYS  
0.54 fl oz (15.8 mL)



### FLONASE ALLERGY RELIEF

fluticasone propionate spray, metered

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0576
<b>Route of Administration</b>	NASAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FLUTICASONE PROPIONATE</b> (UNII: O2GMZ0LF5W) (FLUTICASONE - UNII:CUT2W21N7U)	FLUTICASONE PROPIONATE	50 ug

#### Inactive Ingredients

Ingredient Name	Strength
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<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>PHENYLETHYL ALCOHOL</b> (UNII: ML9LGA7468)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0576-01	1 in 1 CARTON	06/30/2016	
1		30 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:0135-0576-02	1 in 1 PACKAGE	12/04/2014	
2		60 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:0135-0576-03	1 in 1 PACKAGE	12/04/2014	
3		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:0135-0576-04	3 in 1 PACKAGE	01/07/2015	
4		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
5	NDC:0135-0576-12	2 in 1 PACKAGE	02/29/2016	
5		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
6	NDC:0135-0576-14	1 in 1 PACKAGE	11/17/2016	
6		144 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
7	NDC:0135-0576-15	2 in 1 PACKAGE	03/20/2017	
7		144 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
8	NDC:0135-0576-16	3 in 1 PACKAGE	03/20/2017	
8		144 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
9	NDC:0135-0576-17	1 in 1 PACKAGE	01/22/2019	
9		72 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
10	NDC:0135-0576-18	1 in 1 PACKAGE	07/01/2021	
10		90 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	NDA205434	12/04/2014	

**Labeler** - Haleon US Holdings LLC (079944263)

Revised: 3/2024

Haleon US Holdings LLC