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

Drug Facts

Active Ingredient (in each spray)

Fluticasone propionate (glucocorticold) 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 ®Allergy Relief help with?

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

Nasal symptoms

Eye symptoms

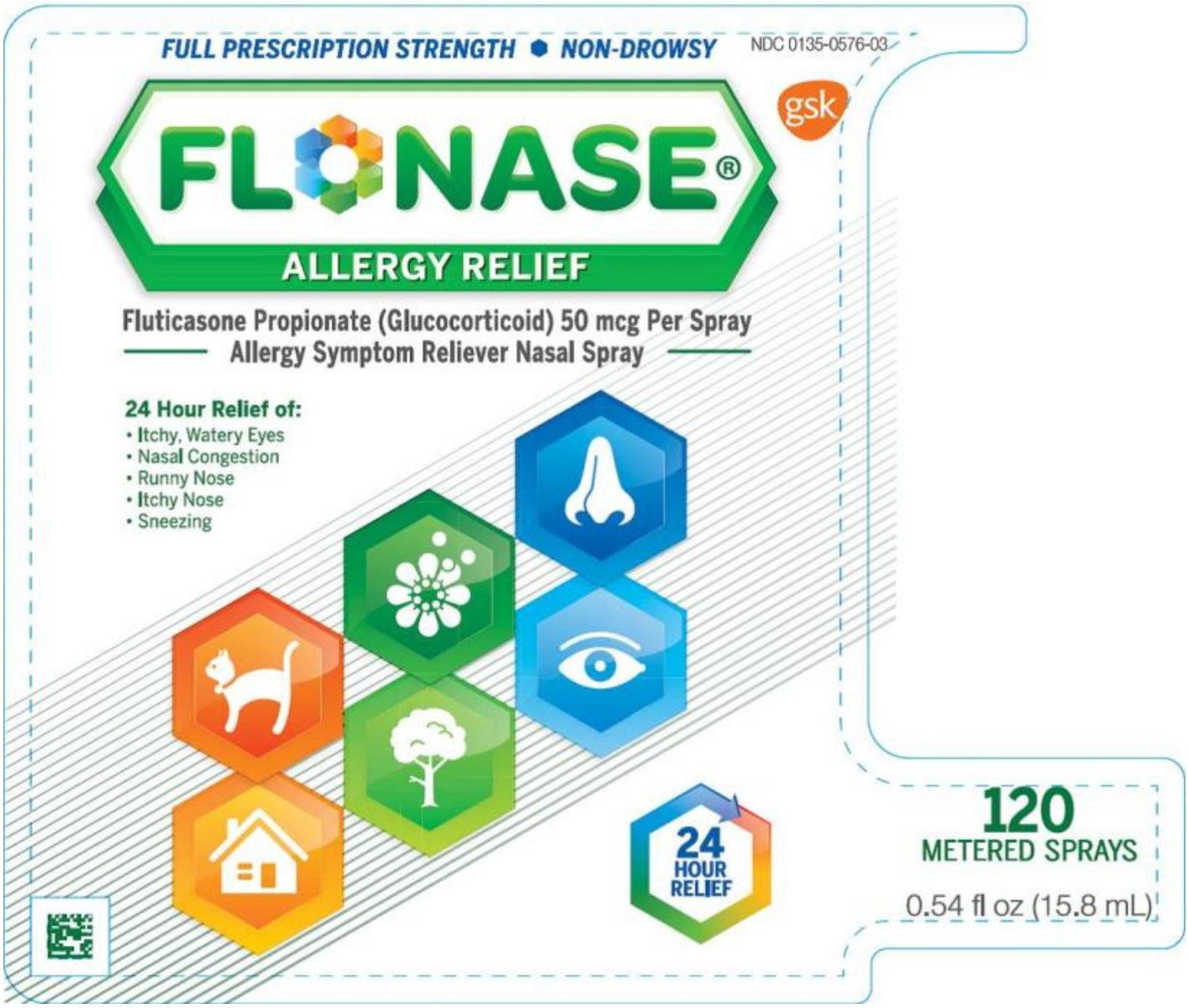
These symptoms can be triggered by allergens like pollen, mold, dust or pet dander.

Outdoor allergens

Animal allergens

Indoor allergens

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



FLONASE ALLERGY RELIEF

fluticasone propionate spray, metered

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0576
Route of Administration	NASAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FLUTICASONE PROPIONATE (UNII: O2GMZ0LF5W) (FLUTICASONE - UNII:CUT2W21N7U)	FLUTICASONE PROPIONATE	50 ug

Inactive Ingredients	
Ingredient Name	**Strength**

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (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

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205434	12/04/2014	

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

Revised: 11/2023 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC