

**FLUTICASONE PROPIONATE ALLERGY RELIEF- fluticasone propionate spray,  
metered  
GLENMARK THERAPEUTICS INC., USA**

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**Drug Facts**

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

Fluticasone propionate (glucocorticoid)\* 50 mcg  
\*read the Question & Answer Leaflet

***Purpose***

Allergy symptom reliever

***Uses***

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

- nasal congestion
- itchy nose
- runny nose
- itchy, watery eyes
- sneezing

***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:
  - o prime the bottle
  - o use the spray
  - o 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, phenylethyl alcohol, polysorbate 80, water for injection, sodium carboxymethylcellulose

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

Call toll-free weekdays 9 AM to 6 PM EST at **1 (844) 721-7115**.

### **Generic Section**

Fluticasone Propionate Nasal Spray Allergy Relief helps relieve a broad range of uncomfortable symptoms like congestion and itchy eyes.

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

Outdoor allergens

Animal allergens

Indoor allergens

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

***TAMPER-EVIDENT*** features for your protection. The product is packaged in a sealed carton. 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.***

### **Principal Display Panel**

FLUTICASONE PROPIONATE NASAL SPRAY, USP

50 mcg per spray

ALLERGY SYMPTOM RELIEVER

(Glucocorticoid)\*

## Non-Drowsy Relief of:

- Nasal congestion
- Itchy, watery eyes
- Itchy nose
- Runny nose
- Sneezing

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

## FULL PRESCRIPTION STRENGTH

## 24 HOUR ALLERGY RELIEF

120 METERED SPRAYS

0.54 fl oz (15.8 mL)

**Drug Facts (continued)**

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Call toll-free weekdays 9 AM to 6 PM EST at 1 (888) 721-7115.

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**CAN HELP WITH:**

- OUTDOOR ALLERGENS
- ANIMAL ALLERGENS
- INDOOR ALLERGENS

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† This product is not manufactured or distributed by GSK Consumer Healthcare/Haleon and/or GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) IP LIMITED, distributor of FLONASE® Allergy Relief and owner of the registered trademark FLONASE®, respectively. (Neither GSK Consumer Healthcare/Haleon nor GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) IP LIMITED make or license Glenmark's product.)



317265711591218

NDC 72657-159-12

<sup>†</sup>Compare to the active ingredient in **FLONASE® Allergy Relief**

FULL PRESCRIPTION STRENGTH  
NON-DROWSY

# FLUTICASONE PROPIONATE NASAL SPRAY, USP

## 50 mcg per spray

**ALLERGY SYMPTOM RELIEVER (Glucocorticoid)\***

**24 HOUR ALLERGY RELIEF**

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

**glenmark**  
Therapeutics<sup>®</sup>

**See below for important information about use in children.**

**Drug Facts**

Active ingredient (in each spray)	Purpose
Fluticasone propionate (glucocorticoid) <sup>†</sup>	Allergy symptom reliever
50 mcg	reliever

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**Directions**

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FLONASE® Allergy Relief (fluticasone propionate) is a steroid medicine known as a glucocorticoid. Do not use if any of these features are torn or damaged.

FLUTICASONE PROPIONATE NASAL SPRAY, USP

Distributed by:  
Glenmark Therapeutics Inc., USA  
Einwood Park, NJ 07407  
www.glenmarkpharma-us.com

MHVDRLUGS/25-AD/097  
12/25  
PE660741225-1



## FLUTICASONE PROPIONATE ALLERGY RELIEF

fluticasone propionate spray, metered

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72657-159
<b>Route of Administration</b>	NASAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>ANHYDROUS DEXTROSE</b> (UNII: 5SL0G7R0OK)	
<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**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:72657-159-60	1 in 1 CARTON	03/16/2026	
1		60 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:72657-159-12	1 in 1 CARTON	03/16/2026	
2		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:72657-159-24	2 in 1 CARTON	03/16/2026	
3		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:72657-159-36	3 in 1 CARTON	03/16/2026	
4		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
5	NDC:72657-159-14	1 in 1 CARTON	03/16/2026	
5		144 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
6	NDC:72657-159-28	2 in 1 CARTON	03/16/2026	
6		144 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
7	NDC:72657-159-42	3 in 1 CARTON	03/16/2026	

7		144 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
8	NDC:72657-159-72	1 in 1 CARTON	03/16/2026	
8		72 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
9	NDC:72657-159-48	4 in 1 CARTON	03/16/2026	
9		120 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
ANDA	ANDA218742	03/16/2026	

**Labeler** - GLENMARK THERAPEUTICS INC., USA (969085666)

## Establishment

Name	Address	ID/FEI	Business Operations
Glenmark Pharmaceuticals Limited		650565703	MANUFACTURE(72657-159)

Revised: 3/2026

GLENMARK THERAPEUTICS INC., USA