

**ALLERGY RELIEF- fluticasone propionate spray, metered  
FSA Store Inc. (Caring Mills)**

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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 (1-800-222-1222) 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**

- **TAMPER EVIDENT:** Do not use if plastic sleeve is torn or broken. 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.**
- 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 carton and enclosed insert. They contain important additional information.

### **Inactive ingredient**

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

### **Questions or comments?**

call **1-877-753-3935** Monday-Friday 9AM-5PM EST

### **Principal display panel**

\*Compare to the active ingredient in Flonase®

Fluticasone Propionate

Nasal Spray (Glucocorticoid,

50 mcg per spray

Allergy Symptom Reliever Nasal Spray

24 Hour Relief

24 hour relief of:

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

- Non drowsy

- Full prescription strength

METERED SPRAYS

FL OZ (mL)

\*This product is not distributed by GlaxoSmithKline, owner of the registered trademark Flonase®.

Manufactured for FSA Store Inc.

601 W 26th St, 3rd Floor

STE 357

DPT# 24075

New York, NY 10001

Package label

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 ■ a steroid medicine for asthma, allergies or skin rash  
 ■ ketoconazole pills (medicine for fungal infection)

**When using this product**  
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 ■ sneezing or sneezing may occur for a few seconds right after use  
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 ■ remember to tell your doctor about all the medicines you take, including this one

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**Drug Facts (continued)**  
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NDC 81522-073-34

\*Compare to the active ingredient in Flonase®

**caring mill™**

**Fluticasone Propionate Nasal Spray (Glucocorticoid), 50 mcg per Spray**  
 Allergy Symptom Reliever Nasal Spray

**24 Hour Relief**

**24 hour relief of:**  
 • Itchy, watery eyes • Nasal congestion  
 • Runny nose • Itchy nose • Sneezing

• Non drowsy  
 • Full prescription strength

**60 Metered Sprays**  
 0.34 FL OZ (9.9 mL)

Manufactured for FSA Store Inc.  
 601 W 26th St, 3rd Floor  
 STE 357  
 DPT# 24075  
 New York, NY 10001

PLD-A772B F0008581

3 59726 07434 6

Lot No.:  
 Exp. Date:

CARING MILL Nasal Spray

**ALLERGY RELIEF**

fluticasone propionate spray, metered

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81522-073
<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
<b>ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE (C12-C16)</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 FORM</b> (UNII: K679OBS311)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81522-073-34	1 in 1 BOX	03/23/2023	
1		60 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	ANDA208024	03/23/2023	

**Labeler** - FSA Store Inc. (Caring Mills) (049283340)

Revised: 3/2023

FSA Store Inc. (Caring Mills)