

# **FLUTICASONE PROPIONATE- fluticasone propionate spray, metered** **Sam's West Inc.**

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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 at 4° to 30°C (39° to 86°F)
- keep this label and enclosed materials. They contain important additional information.

### ***Inactive ingredients***

0.02% w/w benzalkonium chloride, dextrose, microcrystalline cellulose and carboxymethylcellulose sodium, 0.25% w/w phenylethyl alcohol, polysorbate 80, purified water

## Questions or comments?

call toll free **1-800-706-5575**, weekdays, 8:30am – 5:00pm Eastern Standard Time

## Principal Display Panel - Carton

### CARTON LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

### Aller-Nose Nasal Spray

### Fluticasone Propionate Nasal Spray, USP

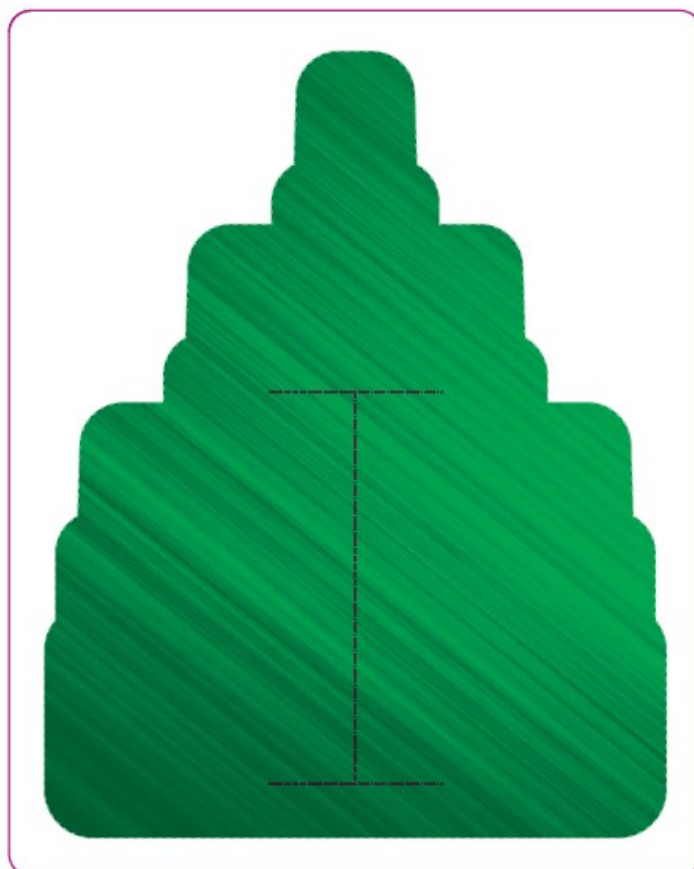
**Apotex Corp.** NDC 68196-210-01


**6 bottles (144 sprays each)**

### Allergy Symptom Reliever Nasal Spray

#### 24 Hour Relief of:

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



Member's Mark 

full prescription strength • non-drowsy

## Aller-Nose Nasal Spray

Fluticasone Propionate, USP

50 mcg per spray

allergy symptom reliever (Glucocorticoid)\*\*

What problems can Fluticasone Propionate Nasal Spray, USP help with?  
Fluticasone Propionate Nasal Spray, USP 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

\*\*Fluticasone propionate is a steroid and should be used as directed only.

Get Further Prescribed Information About Use in Children

Drug Facts	Drug Facts (continued)	Drug Facts (continued)
<b>Active ingredient</b> (In each spray) Fluticasone propionate (USP) Allergy symptom reliever	<b>Purpose</b> To relieve nasal symptoms like congestion and itchy eyes.	<b>Caution</b> • <b>USE IN CHILDREN</b> Do not use in children under 6 years of age. Do not use in children under 6 years of age who are taking other nasal sprays. Do not use in children under 6 years of age who are taking other nasal sprays.
<b>Uses</b> Temporarily relieve these symptoms of hay fever or other upper respiratory allergies: • nasal congestion • runny nose • itchy nose • itchy, watery eyes	<b>Warnings</b> • Do not use if you are pregnant or breastfeeding. • Do not use if you are taking other nasal sprays. • Do not use if you are taking other nasal sprays.	<b>Other information</b> • Do not use if you are pregnant or breastfeeding. • Do not use if you are taking other nasal sprays. • Do not use if you are taking other nasal sprays.
<b>Directions</b> • Shake well before use. • Spray 1-2 times into each nostril 2-3 times daily. • Do not use more than 2 times daily.	<b>Directions</b> • Shake well before use. • Spray 1-2 times into each nostril 2-3 times daily. • Do not use more than 2 times daily.	<b>Directions</b> • Shake well before use. • Spray 1-2 times into each nostril 2-3 times daily. • Do not use more than 2 times daily.

**TAMPER EVIDENT: ON ANY ONE OF THESE PACKAGES, THERE WILL BE A PINCH OR A FINGER ON THE SEAL AND ON THE PINCH LABELS**

**Questions or Comments?**  
We would love to hear about your Member's Mark experience! Call us at: 1-800-706-5575 (toll-free).  
8:30am – 5:00pm EST Monday – Friday

**2D FPO**

DESTROYED BY SANITARY, INC.  
BOSTONVILLE, OH 44024  
PRODUCT OF CANADA

1 73968 1401 5

## Principal Display Panel - Bottle

## BOTTLE LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

### Aller-Nose Nasal Spray

### Fluticasone Propionate Nasal Spray, USP

Apotex Corp. NDC 68196-210-02

144 sprays 0.62 fl oz (18.2 mL)

### Allergy Symptom Reliever Nasal Spray

Member's Mark  NDC 68196-210-02

**Allergy Relief**

FLUTICASONE PROPIONATE NASAL SPRAY, USP

**24 Hour Relief of:**

 • ITCHY WATERY EYES • RUNNY NOSE  
• NASAL CONGESTION • SNEEZING

**144 METERED SPRAYS 0.62 FL OZ (18.2 ML)**

**IMPORTANT:** Read Drug Facts label and enclosed materials for important information. Children 4-11: 1 spray per nostril per day. Talk to a doctor if your child needs to use for longer than two months a year. Keep out of reach of children. Only for use in the nose, do not spray into eyes. Store between 4° and 30°C (39° and 86°F). Shake gently before each use.

\*This product is not manufactured or distributed by GlaxoSmithKline Consumer healthcare, L.P., distributor of Flonase® Allergy Relief Nasal Spray. Flonase® is a registered trademark of GlaxoSmithKline Consumer healthcare, L.P.

For comments or suggestions, call us toll-free at 1-800-706-5575 from 8:30 a.m. to 5:00 p.m. EST Monday - Friday

DISTRIBUTED BY SAM'S WEST, INC. BENTONVILLE, AR 72716 466347

## FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-210
Route of Administration	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>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)	
<b>PHENYLETHYL ALCOHOL</b> (UNII: ML9LGA7468)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:68196-210-02	144 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	01/27/2021	
2	NDC:68196-210-01	6 in 1 CARTON	01/27/2021	
2		6 in 1 BOTTLE, SPRAY; 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	ANDA208150	01/27/2021	

Labeler - Sam's West Inc. (051957769)

Registrant - Apotex Inc. (209429182)