

**FLUTICASONE PROPIONATE- fluticasone propionate spray, metered**  
**Walmart**

-----

**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?***

**1-888-287-1915**

**Principal Display Panel - Carton (60md)**

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

**Walmart NDC 49035-362-01**

**Fluticasone Propionate Nasal Spray, USP**

**60 sprays**

**Allergy Symptom Reliever Nasal Spray**

**24 Hour Relief of:**

- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing

UNSEALED FOR YOUR PROTECTION. IS BROKEN OR DAMAGED, TIGHTEN CAP. IF THE SEAL AROUND THE PRODUCT IS BROKEN, TIGHTEN CAP. IF THE SEAL IS BROKEN, DO NOT USE. BE CAREFUL TO OPEN. TIGHTEN CAP.



**Drug Facts (continued)**

- 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

**Drug Facts (continued)**

**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**

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?**  
1-888-287-1915

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716  
PRODUCT OF CANADA  
\*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare. LP Flonase® is a registered trademark of Glaxo Group Limited.

**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

Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments please call 1-888-287-1915.

NDC 49035-362-01

**equate™**

Compare to Flonase® Allergy Relief active ingredient\*

**Non-Drowsy**

**Allergy Relief**

**Fluticasone Propionate Nasal Spray, USP**

**50 mcg Per Spray**

**Allergy Symptom Reliever (Glucocorticoid)\*\***

**24 Hour Relief of:**

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

**Full Prescription Strength**

**60 Metered Sprays**

**0.34 fl oz (9.9 mL)**



**See Below For Important Information About Use In Children**

**Drug Facts**

**Active ingredient (in each spray) Purpose**

Fluticasone propionate (glucocorticoid)  
50 mcg..... 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
- ketconazole 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



ING2243-0





**Principal Display Panel - Bottle (60md)**

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

**Walmart NDC 49035-362-01**

**Fluticasone Propionate Nasal Spray, USP**

60 sprays

Allergy Symptom Reliever Nasal Spray

**FLUTICASONE PROPIONATE**

fluticasone propionate spray, metered

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49035-362
<b>Route of Administration</b>	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)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
DEXTROSE (UNII: IY9XDZ35W2)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-362-01	1 in 1 CARTON	10/23/2017	
1		60 in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208150	10/23/2017	

**Labeler** - Walmart (051957769)

**Registrant** - Apotex Inc. (209429182)

## Establishment

Name	Address	ID/FEI	Business Operations
Apotex Inc.		255092496	analysis(49035-362) , manufacture(49035-362)

## Establishment

Name	Address	ID/FEI	Business Operations
Legacy Pharmaceutical Packaging		143213275	pack(49035-362)

## Establishment

Name	Address	ID/FEI	Business Operations
Jones Contract Packaging Services		243697187	pack(49035-362)

Revised: 4/2018

Walmart