

ALLERGY RELIEF- fluticasone propionate spray, metered
Discount Drug Mart

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, water 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

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 - Bottle 120ms

BOTTLE LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

Discount Drug Mart NDC 53943-006-01

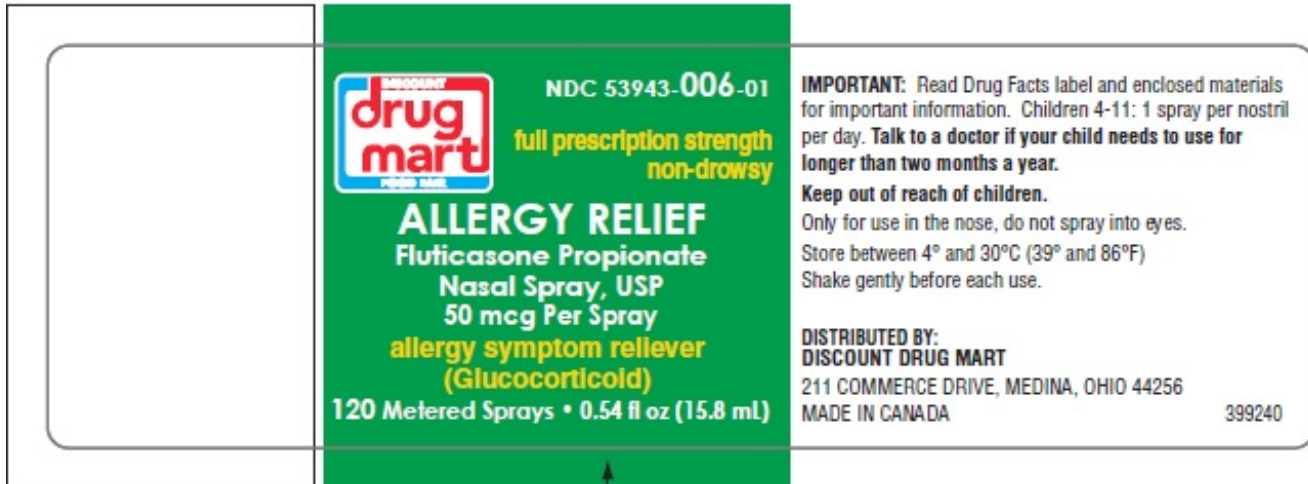
Allergy Relief

Fluticasone Propionate Nasal Spray, USP

120 sprays

Allergy Symptom Reliever Nasal Spray

(Glucocorticoid)



Principal Display Panel - Carton 120ms

CARTON LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

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Allergy Relief

Fluticasone Propionate Nasal Spray, USP

120 sprays

Allergy Symptom Reliever Nasal Spray

24 Hour Relief of:

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

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DANGER: DON'T USE IF CAP OR IS OPENED, TO KNOW
IF THE SEAL AROUND THE PRODUCT LABEL HAS
BROKEN OR IF THERE IS A BUBBLE OR CRACK

Drug Facts (continued)

- remember to tell your doctor about all the medicines you take, including this one

Stay away and ask a doctor if you have, or come into contact with someone who has, chicken pox, measles or shingles

- 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 see 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 do not stop after starting this product
- you have severe or frequent nosebleeds
- if pregnant or breast-feeding, ask a health professional before use.

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

*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, L.P., distributor of Flonase®

Drug Facts (continued)

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER

- Week 1 - use 2 sprays in each nostril once daily
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- 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 liberal 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 59° (9° and 85°F)
- keep this label and enclosed materials. They contain important additional information.

Each ingredient's

0.02% w/v benzalkonium chloride, 0.02% w/v microcrystalline cellulose and carbonyl methylcellulose sodium, 0.25% w/v phenylethyl alcohol, polyethylene glycol 90, purified water

Questions or comments?

call toll free 1-800-706-6675, weekdays, 9:30am - 5:00pm Eastern Standard Time

COMPARE TO THE ACTIVE INGREDIENT OF FLONASE®

full prescription strength • 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

120 Metered Sprays
0.54 fl oz (15.8 mL)

SATISFACTION GUARANTEED

IF DISSATISFIED, RETURN UNUSED PORTION AND PACKAGE TO STORE WHERE PURCHASED. IF UNABLE TO RETURN TO STORE, SEND REASON FOR DISSATISFACTION, NAME, ADDRESS AND EMPTY PACKAGE TO: DISCOUNT DRUG MART, 211 COMMERCE DRIVE, MEDINA, OHIO 44256

DISTRIBUTOR BY: DISCOUNT DRUG MART, 211 COMMERCE DRIVE, MEDINA, OHIO 44256

MADE IN CANADA

See Below For Important Information About Use in Children

Drug Facts

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

Fluticasone propionate (glucocorticoid) Allergy symptoms relief

50 mcg

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
- hormonal or phosphate pills (medicine for fungal infection)

When using this product

- the growth rate of some children may be slower
- dizziness or sneezing may occur for a few seconds right after use
- do not share this bottle with anyone else as this may spread germs

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ALLERGY RELIEF

fluticasone propionate spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-006
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)	

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:53943-006-02	1 in 1 CARTON	07/03/2017	
1		60 in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:53943-006-01	1 in 1 CARTON	07/03/2017	
2		120 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	07/03/2017	

Labeler - Discount Drug Mart (047741335)

Registrant - Apotex Inc. (209429182)

Establishment

Name	Address	ID/FEI	Business Operations
Apotex Inc.		255092496	analysis(53943-006) , manufacture(53943-006)

Revised: 3/2018

Discount Drug Mart