

FLUTICASONE PROPIONATE- fluticasone propionate spray, metered

Chain Drug Marketing Association

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:
 - 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

Quality Choice NDC 83324-294-01

Fluticasone Propionate Nasal Spray, USP

144 sprays

Allergy Symptom Reliever Nasal Spray

24 Hour Relief of:

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



Principal Display Panel - Bottle
 BOTTLE LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray
 Quality Choice NDC 83324-294-01
 Fluticasone Propionate Nasal Spray, USP
 144 sprays
 Allergy Symptom Reliever Nasal Spray



Allergy Relief

Fluticasone Propionate
Nasal Spray, USP
50 mcg Per Spray

Allergy Symptom
Reliever (glucocorticoid)

144 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.

Distributed by CDMA, Inc.
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

Manufactured by:
Apotex Inc.
Toronto, Ontario
Canada M9L 1T9

MADE IN CANADA

FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-294
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, UNSPECIFIED (UNII: K679OBS311)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
DEXTROSE, UNSPECIFIED FORM (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:83324-294-01	1 in 1 CARTON	05/30/2024	
1		144 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	05/30/2024	

Labeler - Chain Drug Marketing Association (011920774)

Registrant - Apotex Inc. (209429182)

Revised: 5/2024

Chain Drug Marketing Association