

FLUTICASONE PROPIONATE- fluticasone propionate spray, metered
Apotex Corp.

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

Allergy Symptom Reliever (Glucocorticoid)

Apotex Corp. NDC 60505-6134-6

Fluticasone Propionate Nasal Spray, USP

6 bottles (120 sprayeach)

Allergy Symptom Reliever Nasal Spray

24 Hour Relief of:

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



full prescription strength • non-drowsy fluticasone propionate nasal spray, 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 medicine known as a glucocorticoid.

See Below For Important Information About Use In Children

Drug Facts	Drug Facts (continued)	Drug Facts (continued)
Active ingredient(s) (in each spray) Fluticasone propionate (glucocorticoid)	Purpose Allergy symptom reliever	Children 4 to 11 Years of Age Use only if your child needs to use the spray for longer than two months a year. Use only if your doctor says so.
Uses Temporarily relieves these symptoms of hay fever or other upper respiratory allergies: • itchy nose • watery eyes • itchy nose • itchy throat	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 • if you have an eye injury or surgery in your nose that is not fully healed • if you have ever had an allergic reaction to this product or any of the ingredients • if you have asthma • if you are pregnant or breastfeeding • if you are taking any medicine for asthma, allergies or other nasal conditions • if you are taking any medicine for fungal infections • if you are using any medicine to help you breathe • if you are using any medicine to help you sleep • if you are using any medicine to help you lose weight • if you are using any medicine to help you lose hair	Other information Keep out of reach of children. • Do not use if you are pregnant or breastfeeding. • Do not use if you are taking any medicine for asthma, allergies or other nasal conditions. • Do not use if you are taking any medicine for fungal infections. • Do not use if you are using any medicine to help you breathe. • Do not use if you are using any medicine to help you sleep. • Do not use if you are using any medicine to help you lose weight. • Do not use if you are using any medicine to help you lose hair.
Directions Only for use in the nose. Do not spray into your eyes or mouth. Do not use: • in children under 4 years of age • if you have an eye injury or surgery in your nose that is not fully healed • if you have ever had an allergic reaction to this product or any of the ingredients • if you have asthma • if you are pregnant or breastfeeding • if you are taking any medicine for asthma, allergies or other nasal conditions • if you are taking any medicine for fungal infections • if you are using any medicine to help you breathe • if you are using any medicine to help you sleep • if you are using any medicine to help you lose weight • if you are using any medicine to help you lose hair	Directions (continued) • Do not use if you are pregnant or breastfeeding. • Do not use if you are taking any medicine for asthma, allergies or other nasal conditions. • Do not use if you are taking any medicine for fungal infections. • Do not use if you are using any medicine to help you breathe. • Do not use if you are using any medicine to help you sleep. • Do not use if you are using any medicine to help you lose weight. • Do not use if you are using any medicine to help you lose hair.	Directions (continued) • Do not use if you are pregnant or breastfeeding. • Do not use if you are taking any medicine for asthma, allergies or other nasal conditions. • Do not use if you are taking any medicine for fungal infections. • Do not use if you are using any medicine to help you breathe. • Do not use if you are using any medicine to help you sleep. • Do not use if you are using any medicine to help you lose weight. • Do not use if you are using any medicine to help you lose hair.

DISTRIBUTED BY:
APOTEX CORP.
WESTON, FL 33320
MADE IN CANADA



100% MONEY BACK GUARANTEE
QUALITY AND PERFORMANCE
We would like to hear from you with any comments or suggestions. In the continental U.S. or Canada, you can call us at 1-800-706-5575 from 8:30 a.m. to 5:00 p.m. EST Monday - Friday.

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED, TORN OR BROKEN OR IF THE SEAL AROUND THE PRODUCT LABEL IS "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

Principal Display Panel - Bottle

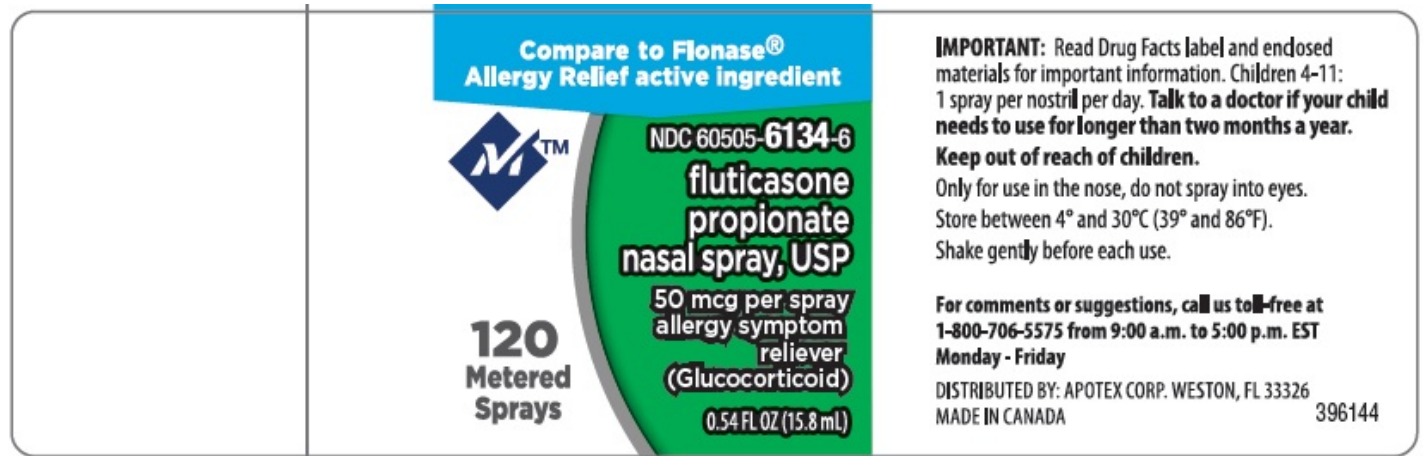
BOTTLE LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

Apotex Corp. NDC 60505-5134-3

Fluticasone Propionate Nasal Spray, USP

120 sprays

Allergy Symptom Reliever Nasal Spray



FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60505-6134	
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 FORM (UNII: K679OBS311)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)				
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60505-6134-3	3 in 1 CARTON	10/25/2016	
1		120 in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:60505-6134-6	6 in 1 CARTON	10/28/2016	
2		6 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	05/31/2016		

Labeler - Apotex Corp. (845263701)

Registrant - Apotex Inc. (209429182)

Establishment

Name	Address	ID/FEI	Business Operations
Apotex Inc.		255092496	analysis(60505-6134) , manufacture(60505-6134)

Establishment

Name	Address	ID/FEI	Business Operations
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Legacy Pharmaceutical Packaging		143213275	pack(60505-6134)
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Establishment

Name	Address	ID/FEI	Business Operations
Jones Pharmaceutical Packaging, LLC		243697187	pack(60505-6134)

Establishment

Name	Address	ID/FEI	Business Operations
HOVIONE FARMACIENCIA, S.A.		449818434	api manufacture(60505-6134)

Revised: 10/2019

Apotex Corp.