

ALLERGY RELIEF- fluticasone propionate spray, metered Cardinal Health (Leader) 70000

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 (1-800-222-1222) 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

- **TAMPER EVIDENT:** Do not use if plastic sleeve is torn or broken. Under the cap and nozzle, each bottle has an aluminum seal around bottle neck. **Do not use if any of these features are torn or damaged.**
- 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 carton and enclosed insert. They contain important additional information.

Inactive ingredient

benzalkonium chloride, carboxymethylcellulose sodium, dextrose, microcrystalline cellulose, phenylethyl alcohol, polysorbate 80, purified water

Questions or comments?

call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal display panel

COMPARE TO FLONASE® active ingredient*

Full Prescription Strength

Fluticasone Propionate

Nasal Spray (Glucocorticoid,

50 mcg per spray

Allergy Symptom Reliever Nasal Spray

Non-Drowsy

24-Hour Relief of:

Itchy, watery eyes,

Itchy Nose, Runny Nose,

Nasal Congestion, Sneezing

METERED SPRAYS

FL OZ (mL)

*This product is not distributed by GlaxoSmithKline, owner of the registered trademark Flonase®.

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

Package label

What problems can Fluticasone Propionate Nasal Spray help with?

Fluticasone Propionate Nasal Spray helps relieve a broad range of uncomfortable symptoms like congestion, runny nose, sneezing, itchy nose and itchy eyes. These symptoms can be triggered by allergens like pollen, mold, dust and pet dander.

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Drug Facts (continued)

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NDC 70000-0613-1

Full Prescription Strength

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Nasal Spray (Glucocorticoid),
50 mcg per spray
Allergy Symptom Reliever Nasal Spray

Non-Drowsy

24-Hour Relief of:
Itchy, Watery Eyes,
Itchy Nose, Runny Nose,
Nasal Congestion, Sneezing

COMPARE TO FLONASE® active ingredient*

100% Money Back Guarantee

120 Metered Sprays

0.54 FL OZ (15.8 mL)

Actual Size

CIN 5804661 REV. 9/22

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.leader.com 1-800-200-6313
Essential to Care® since 1979

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Return to place of purchase.

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Lot No.:
Exp. Date:

LEADER Allergy Reliever Nasal Spray

ALLERGY RELIEF

fluticasone propionate spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0613
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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FLUTICASONE PROPIONATE (UNII: O2GMZ0LF5W) (FLUTICASONE - UNII:CUT2W21N7U)	FLUTICASONE PROPIONATE	50 ug
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Inactive Ingredients	
Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0613-1	1 in 1 BOX	01/31/2023	
1		120 in 1 BOTTLE; 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	ANDA208024	01/31/2023	

Labeler - Cardinal Health (Leader) 70000 (063997360)

Revised: 2/2023

Cardinal Health (Leader) 70000