

FLUTICASONE PROPIONATE- fluticasone propionate spray, metered
Little Pharma, Inc.

380- Health A2Z Nasal Spray

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:

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

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

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 daily
- Week 2 through 6 months: use 1 or 2 sprays in each nostril once daily, as needed to treat symptoms
- After 6 months of daily use: ask a doctor if you can keep using

CHILDREN 4 to 11 YEARS OF AGE

- the growth 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 2 months a year.
- an adult should supervise use
- use 1 spray in each nostril 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 4º and 30ºC (39º and 86ºF)
- 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 1-888-952-0050

Monday through Friday 9AM - 5PM EST

Principal Display Panel

See Below For Important Information About Use in Children

Drug Facts

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Drug Facts (continued)

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Monday through Friday 9AM – 5PM EST

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

Distributed by:
Little Pharma, Inc. New York, NY 10023
Made in Canada

curist

Allergy Nasal Spray

Fluticasone Propionate (Glucocorticoid) 50 mcg per Spray Allergy Symptom Reliever

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

120 Metered Sprays
0.54 fl oz (15.8 mL)

curistrelief.com

Allergy Nasal Spray

FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72559-002
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Route of Administration	NASAL
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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:72559-002-01	1 in 1 CARTON	05/17/2017	
1		120 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	05/17/2017	

Labeler - Little Pharma, Inc. (074328189)

Registrant - Allegiant Health (079501930)

Revised: 4/2019

Little Pharma, Inc.