

FLUTICASONE PROPIONATE- fluticasone propionate spray, metered

Allegiant Health

448 -Childrens Fluticasone Propionate Nasal Spray

Active ingredient(s)

Fluticasone propionate (glucocorticoid) 50 mcg per spray

Purpose

Allergy symptom reliever

Use(s)

Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

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

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

- 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 before use 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 breastfeeding,

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 4° and 30°C (39° and 86°F)
- keep this carton 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/Comments

Call **1-888-952-0050**

(Monday-Friday 9 AM - 5 PM EST)

Principal Display Panel

HealthA2Z®
Children's Fluticasone Propionate Nasal Spray, USP
 50 mcg per spray
24 hours

HealthA2Z®
Children's Fluticasone Propionate Nasal Spray, USP
 50 mcg per spray
24 hours

Relief of:

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

Full Prescription Strength
72 Metered Sprays
 0.38 fl oz (11.1mL)

3 69168 01401 5

Drug Facts (continued)
 If you get a constant whitening around your nose. This may be a sign of damage inside your nose. If you get an allergic reaction to this product. Seek medical help right away. If you get new changes to your vision that develop after starting the product. If 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 use. Prime the bottle. Use the spray. Clean the spray nozzle. Rinse 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.

ADULTS AND 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 carton 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

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

MADE IN CANADA
 L82406
 Manufactured for: R0326
 Allergan Health
 Deer Park, NY 11729

UNVARNISHED

Lot:
Exp:

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.

Nasal symptoms
 Eye Symptoms

These symptoms can be triggered by allergens like pollen, mold, dust or pet dander.

Outdoor allergens
 Animal allergens
 Indoor allergens

Drug Facts
Active ingredient (in each spray)
 Fluticasone propionate, Allergy symptom reliever (glucocorticoid) 50 mcg
Purpose
 Allergy symptom reliever
Uses
 Temporarily relieves these symptoms of hay fever or other upper respiratory allergen:
 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 diabetes or cataracts.
Ask a doctor or pharmacist before use if you are taking:
 medicine for HIV infection (such as zalcitabine)
 a steroid medicine for asthma, allergies or skin rash
 an antibiotic medicine for fungal infection
When using this product:
 the growth rate of some children may be slower
 stopping 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.

Carton Children's Nasal Spray

HealthA2Z[®] NDC 69168-014-01

Children's
Fluticasone Propionate
Nasal Spray, USP
50 mcg per spray

Allergy Symptom Reliever
(Glucocorticoid)

72 Metered Sprays
0.38 fl oz (11.1 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.

Manufactured for:
Allegiant Health
Deer Park, NY 11729

Made in Canada

LB2465
R0326

Label Children's Nasal Spray
Ins

Fluticasone Propionate Nasal Spray, USP

QUICK START GUIDE

HOW TO START GETTING ALLERGY RELIEF RIGHT NOW

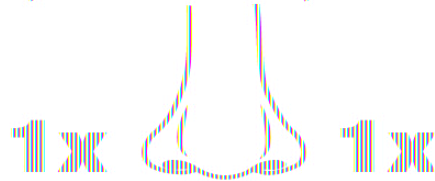


USE THE RIGHT DOSE

Fluticasone Propionate Nasal Spray, USP works best when you use it daily. Here's how to get started.

Children age 4-11

An adult should supervise use.
Use one spray in each nostril once daily.



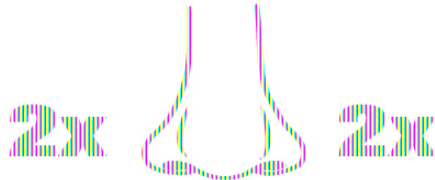
Don't use more than one spray in each nostril per day.

If you miss a dose, just use your regular dose the next day.
Don't add an extra dose.

Check with a doctor if a child needs to use Fluticasone Propionate Nasal Spray, USP for longer than two months a year.

Users age 12 or older

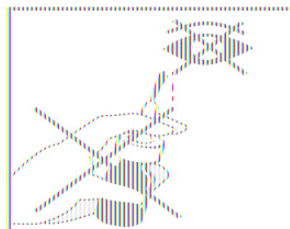
In your first week
Use two sprays in each nostril every day. Don't use more than two sprays in each nostril per day.



After your first week
If your symptoms are under control, you may reduce to one spray in each nostril every day. If your symptoms get worse, go back to two sprays in each nostril.

If you miss a dose, just use your regular dose the next day.
Don't add an extra dose.

WARNING: Do not spray in your eyes. Only for use in your nose.



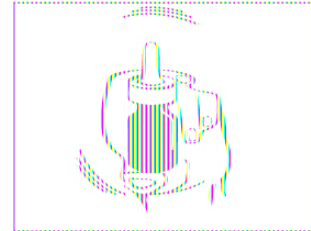
© 2014 Sunovion, Inc. All rights reserved.



GET THE RELIEF YOU NEED

Fluticasone Propionate Nasal Spray can help relieve your allergy symptoms. For best results, it's important to use it daily. Here's how, in five easy steps:

1 Shake



Gently shake spray bottle.



Remove cap.

2 Prime



Do this when:

- Starting new bottle
- Haven't used it in a week
- Just cleaned nozzle

Otherwise go to step 3

Aim away from face. Grasp spray bottle as shown. A fine mist appears.

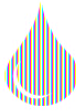
Pumped six times and still no mist? Spray is clogged. See **KEEP IT CLEAN**.

3 Blow



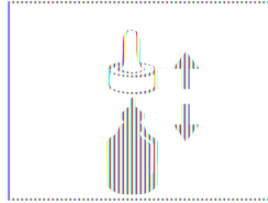
Blow nose gently to clear nostrils.

4 Aim

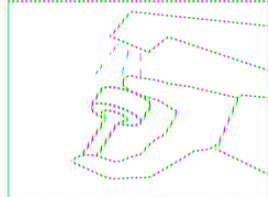


KEEP IT CLEAN

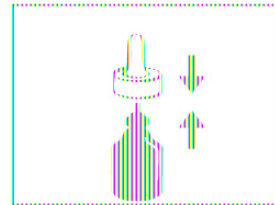
A clean spray nozzle helps ensure a full dose. Clean it weekly, or if it's clogged. Don't try to unblock nozzle with pin or sharp object – that can damage it.



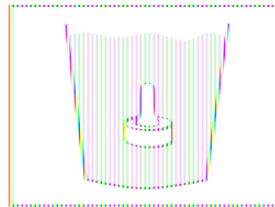
1) Remove spray nozzle by grasping at base and pulling up.



2) Rinse under running tap, and dry at room temperature.



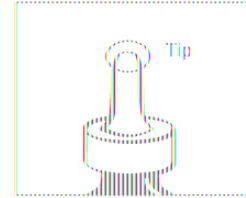
3) Aim away from your face and gently replace spray nozzle until you hear a soft click.



If spray nozzle is clogged, soak in warm water. Then repeat steps 2 and 3.



Close one nostril and put tip of spray nozzle



Put just the tip into your nose.



Aim spray from side

5 Breathe and



While sniffing gently, press down on spray (according to dosing instructions). You'll feel nose. Breathe out through your mouth.

Repeat in other nostril.

Wipe spray nozzle with clean tissue and dry.

Insert Back

FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69168-014

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)	
DEXTROSE (UNII: IY9XDZ35W2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-014-01	1 in 1 CARTON	04/30/2026	
1		72 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	ANDA208150	04/30/2026	

Labeler - Allegiant Health (079501930)

Revised: 4/2026

Allegiant Health