

FLUTICASONE PROPIONATE- fluticasone propionate spray, metered

Allegiant Health

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:

- 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

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 4° and 30°C (39° and 86°F)
- keep this carton and enclosed materials. They contain important additional information.

Inactive ingredients

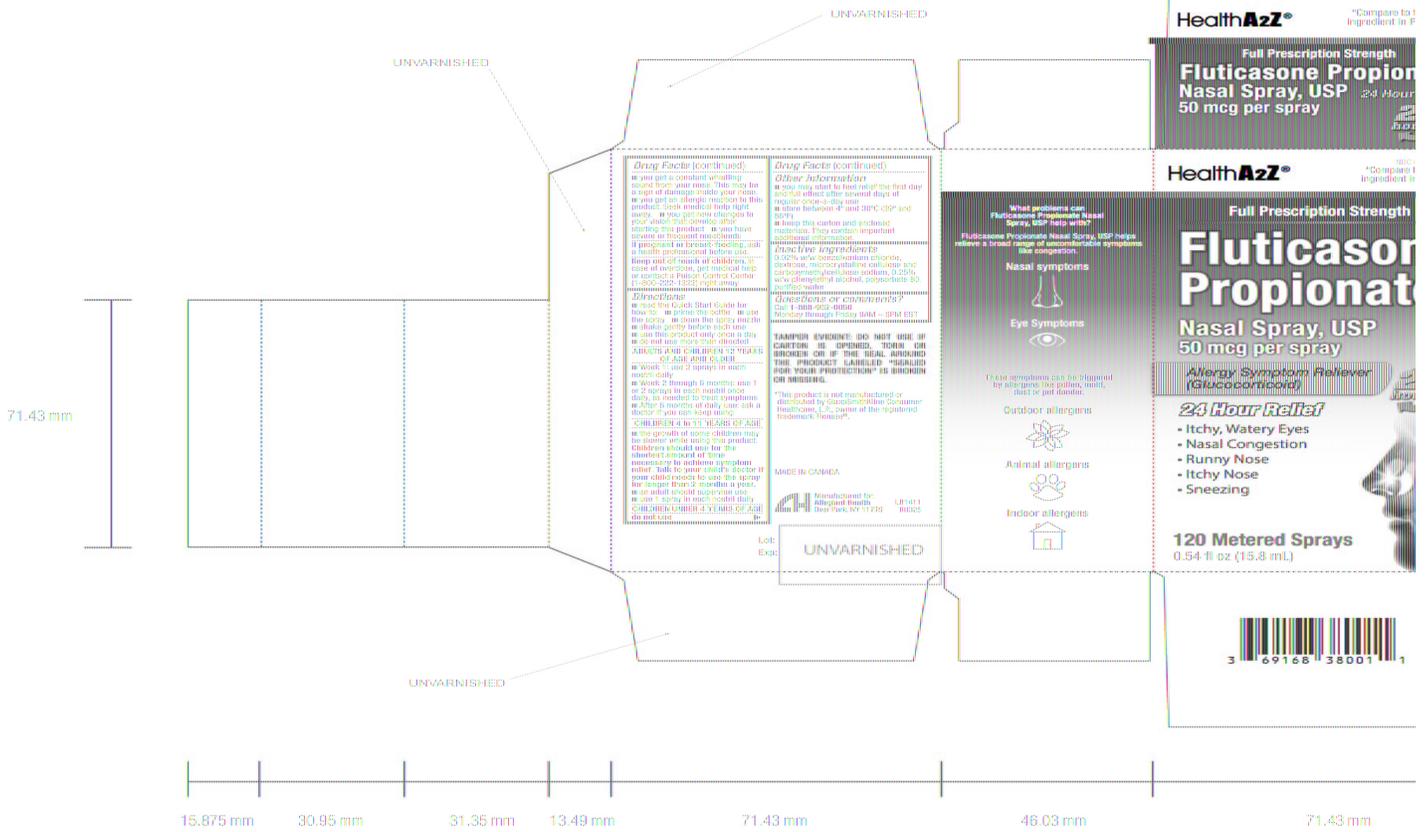
0.02% w/w benzalkonium chloride, dextrose, microcrystalline cellulose and carboxymethylcellulose sodium, 0.25% w/w phenylethyl alcohol, polysorbate 80, purified water

Questions or comments

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

Monday through Friday 9AM – 5PM EST

Principal Display Panel



Carton

HealthA2Z[®]

Fluticasone Propionate

Nasal Spray, USP

50 mcg per spray

Allergy Symptom Reliever
(Glucocorticoid)

120 Metered Sprays
0.54 fl oz (15.8 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:
Allegiant Health
Deer Park, NY 11729

Made in Canada

LB1410
R0118

Label



FLUTICASONE PROPIONATE NASAL SPRAY, USP QUESTIONS & ANSWERS

WHAT FLUTICASONE PROPIONATE NASAL SPRAY, USP IS, HOW TO USE IT, AND WHAT TO EXPECT.

UNDERSTANDING FLUTICASONE PROPIONATE NASAL SPRAY, USP

What Fluticasone Propionate Nasal Spray, USP is, and how it works.

What is Fluticasone Propionate Nasal Spray, USP?

Fluticasone Propionate Nasal Spray, USP is an effective, allergy medicine that you can now buy without a prescription. It works directly in the nose to help block your allergic reactions. Fluticasone Propionate Nasal Spray, USP relieves allergy symptoms caused by pollen, mold, dust and pets.

What is the active ingredient in Fluticasone Propionate Nasal Spray, USP?

The active ingredient in Fluticasone Propionate Nasal Spray, USP is called fluticasone propionate. Fluticasone propionate is a glucocorticoid -- a substance produced naturally by your body to help fight inflammation. It works in your nose to relieve your allergy symptoms. Barely any of it travels through your body. It's been

prescribed by doctors for over 20 years, and used effectively by millions.

A glucocorticoid is a kind of steroid that is different from the anabolic (muscle-building) steroids sometimes misused by athletes. In fact, world class athletes are allowed to use glucocorticoids during competition to treat their allergies.

Who should not use Fluticasone Propionate Nasal Spray, USP?

For complete guidance, check the Drug Facts label on the back of the Fluticasone Propionate Nasal Spray, USP package.

Can I use Fluticasone Propionate Nasal Spray, USP for asthma?

No, Fluticasone Propionate Nasal Spray, USP is not a treatment for asthma. Ask your doctor what medicine to take for your asthma.

Can I use Fluticasone Propionate Nasal Spray, USP for colds?

No, use Fluticasone Propionate Nasal Spray, USP to treat only your allergies--not your cold symptoms. If you're not sure whether your symptoms come from allergies or a cold, ask your doctor.

What happens when you have allergies?

Allergies start when allergens like pollen or pet dander enter your body and trigger your immune system to respond.

Your body's natural response is to release multiple inflammatory substances, (also referred to as mediators) that cause your allergy symptoms.



How does Fluticasone Propionate Nasal Spray, USP work?

Fluticasone Propionate Nasal Spray, USP works right in your nose to help block your allergic reaction at the source to relieve the symptoms that make you uncomfortable.

Fluticasone Propionate Nasal Spray, USP acts on multiple inflammatory substances, including histamine, prostaglandins, cytokines, trypases, chemokines and leukotrienes.

Most common histamine al

Because of it several days Nasal Spray effect. That Fluticasone regularly, on

Fluticasone not only rel and runny n congestion.

What pro Propionate i

Allergies c symptoms eyes. These by allergins) dander

Fluticasone USP helps symptoms f

For example, Fluticasone Propionate Nasal Spray, USP helps with:

Symptoms



Triggers



Nasal Symptoms

- Congestion
- Runny Nose
- Sneezing
- Itchy nose

Eye Symptoms

- Itchy Eyes
- Watery Eyes

Outdoor allergens

- Weed pollen
- Grass pollen
- Tree pollen
- Mold spores

Animal allergens

- Cats
- Dogs

Indoor al

- Dust
- Dust m
- Mold

Who should not use Fluticasone Propionate Nasal Spray, USP or check with a doctor first?

Some people should not use Fluticasone Propionate Nasal Spray, USP, or need to check with a health professional first. This table offers a quick summary of these situations.

If you...	Here's what to do...
Are younger than 4.	Do not use Fluticasone Propionate Nasal Spray, USP.

If you...	Here's what to do...
Are pregnant or breast-feeding	Talk to a health professional before using Fluticasone Propionate Nasal Spray, USP.
Have or had glaucoma or cataracts	Talk to your doctor before using Fluticasone Propionate Nasal Spray, USP.
Have an injury or surgery to your nose that is not fully healed.	Do not use Fluticasone Propionate Nasal Spray, USP.

If you...	Here's what to do...
Have ever had an allergic reaction to Fluticasone Propionate Nasal Spray, USP or any of its ingredients.	Do not use Fluticasone Propionate Nasal Spray, USP.
Are taking a medicine for HIV infection (such as ritonavir)	Talk to your doctor or pharmacist before using Fluticasone Propionate Nasal Spray, USP.

If you...
Are taking ketoconazole pills (medicinal fungal infection)
Are using a steroid medicine for asthma, allergies, skin rash, allergic reactions, inflammatory eye condition

USING FLUTICASONE PROPIONATE NASAL SPRAY, USP

How to get the best results with Fluticasone Propionate Nasal Spray, USP

Read the Drug Facts label on the back of the package or the Quick Start Guide on the other side for simple directions on using Fluticasone Propionate Nasal Spray, USP.

Watch for bold text - it shows where there is different information for children ages 4-11, compared to users age 12 or older.

If you still have questions about using Fluticasone Propionate Nasal Spray, USP after reading the Quick Start Guide, read this section for answers.

I know how to use a nasal spray. Why do I have to follow the directions?

If you don't use the spray bottle correctly, you might not get a full dose. Without a full dose each time, you might not get the relief you deserve.

Follow the simple directions in the Quick Start Guide on the other side.

of Fluticasone Propionate Nasal Spray, USP for a shorter period of time.

Ages	Children 4-11 years of age	Users 12 years of age and older
Dosage	1 spray in each nostril once daily	Up to 2 sprays in each nostril once daily
Duration before checking with a doctor	Up to 2 months of use a year	Up to 6 months of daily use

Why is the use of Fluticasone Propionate Nasal Spray, USP for children age 4-11 limited to 2 months a year before checking with a doctor?

When used long-term, intranasal glucocorticoids like Fluticasone Propionate Nasal Spray, USP may cause the growth rate of some children to be slower. Whether this will affect a child's ultimate height is not known. As a precaution, 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

you insert the nozzle in your nose.

Can I spray Fluticasone Propionate Nasal Spray, USP in my eyes or mouth?

No, Fluticasone Propionate Nasal Spray, USP is meant to work only in your nose to relieve your allergy symptoms, including itchy, watery eyes.



Never spray Fluticasone Propionate Nasal Spray, USP in your eyes or your mouth.

Some decongestants may increase blood pressure. Does Fluticasone Propionate Nasal Spray, USP increase blood pressure?

When used as directed, Fluticasone Propionate Nasal Spray, USP does not increase blood pressure.

Won't I waste product by priming?

It's not a waste to prime the pump, because it helps you get a full dose.

If the label says...

- 30 sprays
- 60 sprays
- 120 sprays
- 150 sprays

Is Fluticasone Propionate Nasal Spray, USP OK to use

You should take the medicine Fluticasone Propionate Nasal Spray, USP as directed and as prescribed. There are a few reasons why you should use Fluticasone Propionate Nasal Spray, USP in your body to

Just to be safe, use the medicine

If my symptoms go away, should I stop using Fluticasone Propionate Nasal Spray, USP?

You may be tempted to stop using Fluticasone Propionate Nasal Spray, USP when you start to feel better. It's important you keep using Fluticasone Propionate Nasal Spray, USP daily as long as you're exposed to allergens that bother you, like pollen, mold, dust or pet dander. This way you'll keep feeling relief.

If you suffer allergy symptoms only during certain times, like when pollen levels are high, you may stop using Fluticasone Propionate Nasal Spray, USP when that time ends. If you are age 12 or older and need to use daily for longer than 6 months or age 4-11 and need to use for longer than 2 months a year, check with your doctor.

What are the differences in the way children age 4-11 should use Fluticasone Propionate Nasal Spray, USP?

Children age 4-11 should use a lower dose

for longer than 2 months a year.

What if I miss a dose by accident?

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

Can I keep using Fluticasone Propionate Nasal Spray, USP year round?

Some people suffer from allergies all year. If you are age 12 or older and have used Fluticasone Propionate Nasal Spray, USP for six months or age 4-11 and have used for two months a year, check with your doctor to make sure it's OK to keep using Fluticasone Propionate Nasal Spray, USP. In fact, it's a good idea for anyone with persistent allergies to talk with a doctor every so often about symptoms and medicines.

Can I share my Fluticasone Propionate Nasal Spray, USP?

Do not share a bottle of Fluticasone Propionate Nasal Spray, USP. Sharing the bottle can spread germs, because

Getting a full dose is important for getting the relief you deserve. See the Quick Start Guide for when and how to prime the pump.

Don't worry about running out due to priming. There is enough medicine in the spray bottle to allow for priming sprays plus the number of sprays labeled on the bottle.

Always point the spray bottle away from your face when priming.

How long should a bottle of Fluticasone Propionate Nasal Spray, USP last?

This table shows roughly how long your bottle will last. It assumes you follow the instructions for priming the pump, and that those age 12 or older use two sprays in each nostril every day while children age 4-11 use one spray in each nostril every day.

After you've used the number of sprays shown on the label, each spray may not deliver a full dose -- even if there is liquid left in the bottle.

you're taking if you're taking

Medicines for HIV infection (such as ritonavir)

Medicines with glucocorticoids including some medicines for skin rash such as eczema, asthma inflammation, allergic reactions or eye conditions

Ketoconazole Pills for fungal infection

WHAT TO EXPECT

What it's like to use Fluticasone Propionate Nasal Spray, USP

How soon will I get relief?

You may start to feel relief the first day you use Fluticasone Propionate Nasal Spray, USP. Keep using it every day, though. It takes several days before Fluticasone Propionate Nasal Spray, USP builds up to full effectiveness.

How long will the relief last?

Fluticasone Propionate Nasal Spray, USP is meant to control your symptoms every day, all day and all night. To help you get this lasting relief, it's important to use Fluticasone Propionate Nasal Spray, USP regularly, once a day.

Does Fluticasone Propionate Nasal Spray, USP cause a "rebound" effect?

No, Fluticasone Propionate Nasal Spray, USP does not cause a rebound effect.

Some nasal decongestant sprays may cause your nasal passages to swell up even more when you use them too often or for longer than their label says you should (three days). This is sometimes called a

"rebound effect."

Fluticasone Propionate Nasal Spray, USP is a different kind of medicine and does not cause any rebound effect. You can use Fluticasone Propionate Nasal Spray, USP for up to six months if you are age 12 or older or up to two months a year if you are age 4-11 before checking with a doctor.

Will Fluticasone Propionate Nasal Spray, USP make me drowsy?

No, Fluticasone Propionate Nasal Spray, USP does not cause drowsiness. Some allergy medications can cause drowsiness, but Fluticasone Propionate Nasal Spray, USP does not.

Why does Fluticasone Propionate Nasal Spray, USP have a smell?

The light floral scent you may notice comes from one of the important ingredients in the Fluticasone Propionate Nasal Spray, USP formula. No fragrance is added to Fluticasone Propionate Nasal Spray, USP.

What if little or nothing is spraying out?

Try priming the spray bottle. It may take a few pumps to get the dispenser spraying again.

If that doesn't work, the spray nozzle may be clogged. You can clean it following the directions in the Quick Start Guide on the other side.

What if I feel stinging in my nose, or I sneeze?

Some people may feel a slight stinging, or may sneeze, after spraying Fluticasone Propionate Nasal Spray, USP in their nostrils. This feeling should go away in a few seconds.

What if I feel or taste the medicine in my throat?

Generally, you can avoid this by taking a shallower breath next time you spray Fluticasone Propionate Nasal Spray, USP into your nostrils. For example, take the kind of breath you would use to smell a flower.

What if I have chicken pox, measles or tuberculosis or come into contact with someone who does?

Stop using Fluticasone Propionate Nasal Spray, USP and ask your doctor.

What if I'm having severe sinus pain?

If you feel severe pain in your face,

have thick nasal mucus, or if you have a fever, stop using Fluticasone Propionate Nasal Spray, USP and see your doctor. You may need to stop using Fluticasone Propionate Nasal Spray, USP and see your doctor.

What if my symptoms don't go away after one week?

If you have used Fluticasone Propionate Nasal Spray, USP for one week and your symptoms are still not controlled, you should see your doctor. You may need to stop using Fluticasone Propionate Nasal Spray, USP and see your doctor.

Does Fluticasone Propionate Nasal Spray, USP have any side effects?

Some side effects of Fluticasone Propionate Nasal Spray, USP include: headache, sore throat, dry mouth, nosebleeds, and irritation of the nose or throat. However, like other corticosteroid nasal sprays, Fluticasone Propionate Nasal Spray, USP may cause side effects in some people.

Here are some of the side effects that have been reported with Fluticasone Propionate Nasal Spray, USP. If you have any concerns about these side effects, talk with your doctor.

Side effect	What could happen	What to do
Allergic reaction to the product	<ul style="list-style-type: none"> Sudden swelling of face or tongue A rash Wheezing or feeling faint 	If you feel any of these symptoms, stop using Fluticasone Propionate Nasal Spray, USP and see a doctor right away.
Nose injury	<ul style="list-style-type: none"> Severe or frequent nosebleeds Constant whistling sound that does not go away 	Apply pressure to your nose. Stop using Fluticasone Propionate Nasal Spray, USP and see a doctor. This could be a sign of damage to your nose. Stop using Fluticasone Propionate Nasal Spray, USP and see a doctor right away.
Eye conditions such as cataracts or glaucoma	<ul style="list-style-type: none"> Cloudy vision Reduced vision 	Have a yearly eye exam to check for these conditions. Read the Drug Facts on the back of the Fluticasone Propionate Nasal Spray, USP package for more details.

Side effect	What could happen	What to do
Growth effects	<ul style="list-style-type: none"> Slower growth rate in some children while using product 	Talk to your doctor if a child is using Fluticasone Propionate Nasal Spray, USP for longer than 6 months.
Other side effects	<ul style="list-style-type: none"> Headaches or sneezing Bad taste or smell Minor nosebleeds Dry or irritated nose or throat 	Talk to your doctor if you are concerned about these side effects.

STILL HAVE QUESTIONS? Call 1-888-9

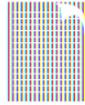
Insert Front



Fluticasone Propionate Nasal Spray, USP

QUICK START GUIDE

HOW TO START GETTING ALLERGY RELIEF RIGHT NOW

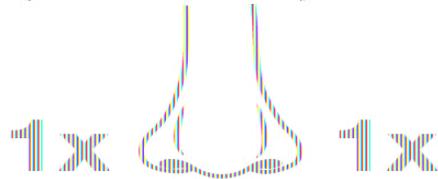


USE THE RIGHT DOSE

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.



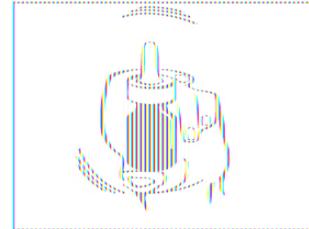
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GET THE RELIEF YOU NEED

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



Aim away from face. Grasp spray bottle as shown.



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.



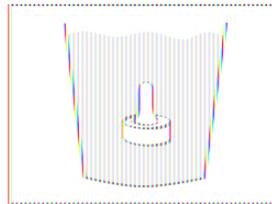
1) Remove spray nozzle by grasping at base and pulling up.



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



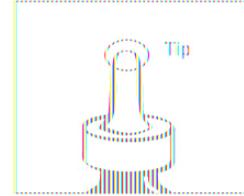
3) Aim away from your face and gently replace spray nozzle until you hear a soft click.



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 corner of eye.

5 Breathe and



While sniffing gently, press down on spray nozzle (according to dosing instructions). You'll feel a soft click. 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:69168-380

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 (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:69168-380-01	1 in 1 CARTON	05/17/2017	
1		120 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:69168-380-02	2 in 1 CARTON	05/17/2017	
2		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	ANDA208150	05/17/2017	

Labeler - Allegiant Health (079501930)

Revised: 11/2017

Allegiant Health