

FLUTICASONE PROPIONATE- fluticasone propionate spray, metered

Allegiant Health

452 - Fluticasone Propionate Nasal Spray 144 Metered 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

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 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 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/Comments

Call 1-888-952-0050 Monday through Friday 9AM to 5PM EST

Principal Display Panel

HealthA2z® *Compare to the active ingredient in FLONASE®

Full Prescription Strength • Non-Drowsy
Fluticasone Propionate
 Nasal Spray, USP **24 Hour Relief**
 50 mcg per spray

HealthA2z® NDC 01104-457-01 *Compare to the active ingredient in FLONASE®

Full Prescription Strength • Non-Drowsy
Fluticasone Propionate
 Nasal Spray, USP **24 Hour Relief**
 50 mcg per spray

Allergy Symptom Reliever (Glucocorticoid) **24 Hours**

24 Hour Relief

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

144 Metered Sprays
 0.62 fl oz (18.2mL)

Drug Facts (continued)

• If you get a constant wheezing sound from 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 this product.
 • If you have severe or frequent nosebleeds.
 • If congested or blocked breathing, and 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 the product.
 • 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: 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 taking.

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 • An adult should supervise use.
 • Use 1 spray in each nostril daily.

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Other information

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 • Store between 4° and 30°C (39° and 86°F).
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Inactive ingredients
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Questions or comments?
 Call 1-888-952-0050
 Monday through Friday 9AM - 5PM EST

Warnings

• Only for use in the nose. Do not spray into the eyes or mouth.
 • Do not use in children under 4 years of age.
 • Do not use if you have an injury or surgery to your nose that is not fully healed.
 • If you have ever had an allergic reaction to the 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:
 • Medicines for HIV infection (such as zidovudine or didanosine).
 • Medicines for asthma, allergies or sinusitis.
 • Medicines for fungal infections.

When using this product

• The growth rate of some children may be slower.
 • If spraying 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.

Keep 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.

What problems can Fluticasone Propionate Nasal Spray, USP help with?

Fluticasone Propionate Nasal Spray, USP helps relieve a broad range of upper respiratory symptoms and 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

MADE IN CANADA L12158 R1223
 Distributed by: Allergan HealthCare, Inc. New York, NY 11739

Lot: UNVARNISHED
 Exp:

X0042T83A5
 HealthA2z® Fluticasone Propionate Nasal Spray, USP
 New

Fluticasone propionate

FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-452
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 (UNII: 05JZI7B19X)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-452-01	1 in 1 CARTON	04/11/2024	
1		144 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	ANDA077538	04/11/2024	

Labeler - Allegiant Health (079501930)

Revised: 4/2024

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