

# **FLUTICASONE PROPIONATE- fluticasone propionate spray, metered**

## **Allegiant Health**

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### **448 - Fluticasone Propionate Nasal Spray 72 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

**Drug Facts (continued)**

■ 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**

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 ■ 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.

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

MADE IN CANADA

**4H** Regulated Health  
Deer Park, NY 11729

Lot: UNVARNISHED  
Exp:

**Drug Facts (continued)**

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**Questions or comments?**  
Call 1-888-952-0050  
Monday through Friday 9AM - 5PM EST

\*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, L.P., owner of the registered trademark Flonase®.

**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

**24 hours**

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**HealthA2Z®** NDC 69168-448-01 \*Compare to the active ingredient in FLONASE®

Full Prescription Strength • Non-Drowsy

**Fluticasone Propionate**  
Nasal Spray, USP 24 Hour Relief  
50 mcg per spray

**24 hours**

**Allergy Symptom Reliever (Glucocorticoid)**

**24 Hour Relief**

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

**72 Metered Sprays**  
0.38 fl oz (11.1mL)

**24 hours**

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**See Below For Important Information About Use in Children**

**Drug Facts**

Active ingredient (in each spray)	Purpose
Fluticasone propionate	Allergy symptom reliever (glucocorticoid), 50 mcg

**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:

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- 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

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**Ask a doctor or pharmacist before use if you are taking:**

- medicine for HIV infection (such as ritonavir)
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- the growth rate of some children may be slower
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## Fluticasone Propionate

HealthA2Z<sup>®</sup> NDC 69168-448-01

**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.

Distributed by:

**Allegiant Health**  
Deer Park, NY 11729

Made in Canada

LB2136  
R0923

## Fluticasone Propionate Label

### FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69168-448
<b>Route of Administration</b>	NASAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FLUTICASONE PROPIONATE</b> (UNII: O2GMZ0LF5W) (FLUTICASONE - UNII:CUT2W21N7U)	FLUTICASONE PROPIONATE	50 ug

#### Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>DEXTROSE</b> (UNII: IY9XDZ35W2)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>PHENYLETHYL ALCOHOL</b> (UNII: ML9LGA7468)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>WATER</b> (UNII: 059QF0KO0R)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-448-01	1 in 1 CARTON	12/10/2023	
1		72 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	ANDA077538	12/10/2023	

**Labeler** - Allegiant Health (079501930)