

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

## **Walmart**

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### **Drug Facts**

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

#### **CHILDREN 4 TO 11 YEARS OF AGE**

- the growth rate 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 two months a year.**
- an adult should supervise use
- use 1 spray in each nostril once 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° to 30°C (39° to 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 or comments?***

call toll free **1-888-287-1915**

## **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 and itchy eyes.

- nasal congestion
- Eye symptoms

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

- Outdoor allergens
- Animal allergens
- Indoor allergens

## **Principal Display Panel - Carton**

**CARTON LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray**

**Walmart Pharmacy** NDC 49035-063-01

**Children's Allergy Relief (Fluticasone Propionate) Nasal Spray, USP**

**60 sprays**

**Allergy Symptom Reliever Nasal Spray**

### **24 Hour Relief of:**

- Nasal Congestion
- Runny Nose
- Sneezing
- Itchy nose
- Itchy, watery eyes



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\*\*Fluticasone propionate is a steroid medicine known as a glucocorticoid.

### Drug Facts (continued)

- 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 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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#### CHILDREN 4 TO 11 YEARS OF AGE

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- an adult should supervise use
- use 1 spray in each nostril once daily

#### CHILDREN UNDER 4 YEARS OF AGE

- do not use

### Drug Facts (continued)

#### 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)
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#### Inactive ingredients

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#### Questions or comments?

1-888-287-1915

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716  
PRODUCT OF CANADA

\*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, LP. The mark RiteCare® is a registered trademark of Glaxo Group Limited plc.

#### 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 and itchy eyes.

- Nasal symptoms
- Eye symptoms
- These symptoms can be triggered by allergens like pollen, mold, dust or pet dander.
- Outdoor allergens
- Animal allergens
- Indoor allergens

Satisfaction guaranteed - For questions or comments please call 1-888-287-1915.

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

NDC 49035-063-01

**equate™**

children's  
**ALLERGY  
RELIEF**

Fluticasone Propionate  
Nasal Spray, USP  
50 mcg Per Spray

Allergy Symptom Reliever  
(Glucocorticoid)\*\*

Full Prescription Strength

**AGES 4 YEARS & OLDER**

#### 24 Hour Relief of:

- Itchy, watery eyes
- Nasal congestion
- Runny nose
- Itchy nose
- Sneezing



- Non-Drowsy
- 60 Metered Sprays

0.34 fl oz (9.9 mL)

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See Below For Important Information  
About Use In Children

### Drug Facts

#### Active ingredient (in each spray) Purpose

Fluticasone propionate  
(glucocorticoid)  
50 mcg ..... 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 you  
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
- ketconazole 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



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**Principal Display Panel - Bottle**

**BOTTLE LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray**

**Walmart Pharmacy NDC 49035-063-01**

**Children's Allergy Relief (Fluticasone Propionate) Nasal Spray, USP**

**60 sprays**

**Allergy Symptom Reliever Nasal Spray**



## Principal Display Panel - Bottle-72md

**BOTTLE LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray**

**Walmart Pharmacy NDC 49035-063-02**

**Children's Allergy Relief (Fluticasone Propionate) Nasal Spray, USP**

**72 sprays**

**Allergy Symptom Reliever Nasal Spray**



## Principal Display Panel - Carton-72md

**CARTON LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray**

**Walmart Pharmacy NDC 49035-063-02**

**Children's Allergy Relief (Fluticasone Propionate) Nasal Spray, USP**

**72 sprays**

**Allergy Symptom Reliever Nasal Spray**

**24 Hour Relief of:**

- Nasal Congestion
- Runny Nose
- Sneezing



- Itchy nose
- Itchy, watery eyes

**Drug Facts (continued)**  
 ■ 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 once daily  
 ■ Week 2 through 6 months - use 1 or 2 sprays in each nostril once daily, as needed to treat your symptoms  
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**CHILDREN 4 TO 11 YEARS OF AGE**  
 ■ the growth rate 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 two months a year.  
 ■ an adult should supervise use  
 ■ use 1 spray in each nostril once daily  
**CHILDREN UNDER 4 YEARS OF AGE**  
 ■ do not use

**Drug Facts (continued)**  
**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 or comments?**  
 call toll free 1-888-287-1915, weekdays, 8:30am-5:00pm Eastern Standard Time

**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 and itchy eyes.  
 • Nasal symptoms • Eye symptoms  
 These symptoms can be triggered by allergens like pollen, mold, dust or pet dander.  
 • Outdoor allergens • Animal allergens • Indoor allergens

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**PRODUCT OF CANADA**  
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Satisfaction guaranteed - For questions or comments please call 1-888-287-1915.

**equatē™**  
**childrens**  
**Allergy Relief**  
**FLUTICASONE PROPIONATE NASAL SPRAY, USP**  
 50 mcg Per Spray (glucocorticoid)\*\*  
**Full Prescription Strength**  
**Ages 4 Years & Older**  
**24 Hour Relief of:**  
 ■ Itchy, Watery Eyes  
 ■ Nasal Congestion  
 ■ Runny Nose  
 ■ Itchy Nose  
 ■ Sneezing

**LASTS UP TO 24 HOURS**  
**Allergy Symptom Reliever**

**Non-Drowsy**  
**72 Metered Sprays**  
**0.38 FL OZ (11.1mL)**

**Drug Facts**  
**Active ingredient (in each spray) Purpose**  
 Fluticasone propionate (glucocorticoid)  
 50 mcg.....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 you 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  
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**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

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PAPER BOX GLASS BOTTLE

# FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-063
Route of Administration	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>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)				
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)				
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)				
<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:49035-063-01	1 in 1 CARTON	10/11/2017	04/06/2024
1		60 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:49035-063-02	1 in 1 CARTON	07/26/2021	
2		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		ANDA208150	10/11/2017	

**Labeler** - Walmart (051957769)

**Registrant** - Apotex Inc. (209429182)