

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

## **Target Corporation**

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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 at 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 **1-800-706-5575**, weekdays, 8:30am – 5:00pm Eastern Standard Time

### Principal Display Panel - Bottle 72md

#### BOTTLE LABEL - PRINCIPAL DISPLAY PANEL

Target Corporation

NDC 11673-262-05

Allergy Relief Nasal Spray

Fluticasone Propionate Nasal Spray, USP

50 mcg per spray

72 sprays

Allergy Symptom Reliever Nasal Spray



### Principal Display Panel - Carton 72md

#### CARTON LABEL - PRINCIPAL DISPLAY PANEL

Target Corporation

NDC 11673-262-04

Allergy Relief Nasal Spray

Fluticasone Propionate Nasal Spray, USP

72 metered sprays

50 mcg per spray

Allergy Symptom Reliever Nasal Spray

#### 24 Hour Relief of:

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

- Sneezing

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**Drug Facts (continued)**

Stop use and ask a doctor if

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- you get new changes to your vision that develop after starting this product
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**Drug Facts (continued)**

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

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 Minneapolis, MN 55403  
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 Made in Canada

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

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

Compare to active ingredient in Flonase®\*\*

Full Prescription Strength

## Non-Drowsy Allergy Relief Nasal Spray

Fluticasone Propionate (Glucocorticoid)\*\*, USP 50 mcg per Spray  
 Allergy Symptom Reliever Nasal Spray

24-Hour relief of itchy watery eyes, nasal congestion, runny nose, itchy nose and sneezing

24  
Hours

72  
Sprays



**up&up**

72 METERED SPRAYS  
 0.38 FL OZ (11.1 mL)

See Below For Important Information About Use In Children

**Drug Facts**

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

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

- nasal congestion
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- itchy nose
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- a steroid medicine for asthma, allergies or skin rash
- antifungal pills (medicines for fungal infection)

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- the growth rate of some children may be slower
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Principal Display Panel - Bottle 144md  
 Target Corporation

**NDC 11673-262-02**

**Allergy Relief Nasal Spray**

**Fluticasone Propionate Nasal Spray, USP**

**50 mcg per spray**

**72 sprays**

**Allergy Symptom Reliever Nasal Spray**



**Principal Display Panel - Carton 144md**

**CARTON LABEL - PRINCIPAL DISPLAY PANEL**

**Target Corporation**

**NDC 11673-262-01**

**Allergy Relief Nasal Spray**

**Fluticasone Propionate Nasal Spray, USP**

**144 metered sprays**

**50 mcg per spray**

**Allergy Symptom Reliever Nasal Spray**

**24 Hour Relief of:**

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



Principal Display Panel - Carton 2x144md  
**CARTON LABEL - PRINCIPAL DISPLAY PANEL**  
**Target Corporation**  
**NDC 11673-262-03**  
**Allergy Relief Nasal Spray**

# Fluticasone Propionate Nasal Spray, USP

2 x 144 metered sprays

50 mcg per spray

Allergy Symptom Reliever Nasal Spray

24 Hour Relief of:

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



## FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11673-262

**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:11673-262-01	1 in 1 CARTON	03/11/2021	
1	NDC:11673-262-02	144 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:11673-262-03	2 in 1 CARTON	03/11/2021	
2	NDC:11673-262-02	144 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:11673-262-04	1 in 1 CARTON	03/11/2021	
3	NDC:11673-262-05	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	03/11/2021	

**Labeler** - Target Corporation (006961700)

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