

FLUTICASONE PROPIONATE- fluticasone propionate spray, metered **The Kroger Co.**

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 (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
- 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°C and 30°C (39°F 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 **1-800-632-6900**

Principal Display Panel - Carton (single)

Principal Display Panel - Bottle

Principle Display Panel - Carton (2x144ms)

COMPARE TO THE ACTIVE INGREDIENT IN FLONASE® ALLERGY RELIEF*

FULL PRESCRIPTION STRENGTH

Allergy Relief

Nasal Spray

FLUTICASONE PROPIONATE, USP

(GLUCOCORTICOID)†

50 mcg PER SPRAY

ALLERGY SYMPTOM RELIEVER

NON-DROWSY

24-HOUR RELIEF OF:

ITCHY, WATERY EYES

NASAL CONGESTION

RUNNY NOSE

ITCHY NOSE

SNEEZING

FL OZ (mL)

*FLONASE® IS A REGISTERED TRADEMARK OF GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) IP LIMITED.

†Fluticasone propionate is a steroid medicine known as a glucocorticoid.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED, TORN OR BROKEN OR IF THE

SEAL AROUND THE PRODUCT LABELLED "SEAL FOR YOUR PROTECTION" IS BROKEN OR MISSING.

PROUDLY DISTRIBUTED
BY THE KROGER CO.
CINCINNATI, OHIO 45202

Package label

<p>See Below For Important Information About Use In Children</p> <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient (in each spray)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Fluticasone propionate (glucocorticoid) 50 mcg</td> <td>Allergy symptom reliever</td> </tr> </tbody> </table> <p>Uses Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> nasal congestion runny nose sneezing itchy nose itchy, watery eyes <p>Warnings Only for use in the nose. Do not spray into your eyes or mouth.</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor before use if you have or had glaucoma or cataracts</p> <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> medicine for HIV infection (such as zidovudine) a steroid medicine for psoriasis, allergies or skin rash antibiotic pills (medicine for fungal infection) <p>When using this product</p> <ul style="list-style-type: none"> the growth rate of some children may be slower sneezing 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 <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you have, or come into contact with someone who has chickenpox, 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 <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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.</p> <p><small>*Fluticasone propionate is a steroid medicine known as a glucocorticoid.</small></p>	Active ingredient (in each spray)	Purpose	Fluticasone propionate (glucocorticoid) 50 mcg	Allergy symptom reliever	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> read the Quick Start Guide for how to: <ul style="list-style-type: none"> 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 <p>ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER</p> <ul style="list-style-type: none"> 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 <p>CHILDREN 4 TO 11 YEARS OF AGE</p> <ul style="list-style-type: none"> 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 <p>CHILDREN UNDER 4 YEARS OF AGE</p> <ul style="list-style-type: none"> do not use <p>Other information</p> <ul style="list-style-type: none"> you may start to feel relief the first day and full effect after several days of regular, once-a-day use store between 4°C and 30°C (39°F and 86°F) keep this label and enclosed materials. They contain important additional information. <p>Inactive ingredients 0.02% w/w benzalkonium chloride, dextrose, microcrystalline cellulose and carboxymethylcellulose sodium, 0.25% w/v phenylethyl alcohol, polyorbate 80, purified water</p> <p>Questions or comments? Call 1-800-632-6900</p> <p><small>*FLONASE® is a registered trademark of GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) IP LIMITED.</small></p>	<p>NDC 30142-258-01</p> <p>Kroger health</p> <p>COMPARE TO THE ACTIVE INGREDIENT IN FLONASE® ALLERGY RELIEF*</p> <p>UP TO 24 HR RELIEF</p> <p>FULL PRESCRIPTION STRENGTH</p> <p>Allergy Relief Nasal Spray</p> <p>FLUTICASONE PROPIONATE, USP (GLUCOCORTICOID)[†] 50 mcg PER SPRAY ALLERGY SYMPTOM RELIEVER NON-DROWSY</p> <p>NOT ACTUAL SIZE</p> <p>24-HOUR RELIEF OF: ITCHY, WATERY EYES NASAL CONGESTION RUNNY NOSE ITCHY NOSE SNEEZING</p> <p>144 METERED SPRAYS 0.62 FL OZ (18.2 mL)</p>	<p>What problems can Fluticasone Propionate Nasal Spray, USP help with?</p> <p>Fluticasone Propionate Nasal Spray, USP helps relieve a broad range of uncomfortable symptoms like congestion and itchy eyes.</p> <ul style="list-style-type: none"> Nasal symptoms Eye symptoms <p>These symptoms can be triggered by allergens like pollen, mold, dust or pet dander.</p> <ul style="list-style-type: none"> Outdoor allergens Animal allergens Indoor allergens <p><small>TAMPER EVIDENT DO NOT USE IF CAPTION IS OPENED, TORN OR BROKEN OR IF THE SEAL AROUND THE PRODUCT LABELLED "SEAL FOR YOUR PROTECTION" IS BROKEN OR MISSING.</small></p> <p>PROUDLY DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202 PRODUCT OF INDIA</p> <p>OUR PHARMACIST RECOMMENDED</p> <p>For More Product Information, Scan UPC Using Your Kroger App or Call 800-632-6900</p> <p>QUALITY GUARANTEED</p> <p>Quality Guaranteed Kroger.com/guarantee 800-632-6900</p>
Active ingredient (in each spray)	Purpose						
Fluticasone propionate (glucocorticoid) 50 mcg	Allergy symptom reliever						
<p>PLD-A903A FC009480</p>  <p>0 41260 01228 0</p>							

KROGER HEALTH Allergy Relief Nasal Spray

Principle Display Panel - Bottle (72ms)

Principle Display Panel - Carton (72ms)

FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-258
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, UNSPECIFIED (UNII: K679OBS311)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-258-01	1 in 1 CARTON	07/01/2025	
1	NDC:30142-258-04	144 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:30142-258-02	2 in 1 CARTON	07/01/2025	
2		144 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:30142-258-03	1 in 1 CARTON	07/01/2025	
3	NDC:30142-258-05	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	07/01/2025	

Labeler - The Kroger Co. (006999528)