

FLUTICASONE PROPIONATE- fluticasone propionate spray, metered

Walgreens

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 - Carton (single)

CARTON LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

Walgreens NDC 0363-0652-01

Allergy Nasal Spray

Fluticasone Propionate 50 mcg per spray

Allergy Symptom Reliever

(Glucocorticoid)

144 sprays

24 Hour Relief of:

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



Principal Display Panel - Bottle

BOTTLE LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

Walgreens NDC 0363-0652-04

Allergy Nasal Spray

Fluticasone Propionate 50 mcg

144 sprays

Allergy Symptom Reliever

(Glucocorticoid)



Principle Display Panel - Carton (2x144ms)

CARTON LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

Walgreens NDC 0363-0652-02

Allergy Nasal Spray

Fluticasone Propionate 50 mcg per spray

2 x 144 sprays

Allergy Symptom Reliever

(Glucocorticoid)

24 Hour Relief of:

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



Principle Display Panel - Carton (4x144ms)

CARTON LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

Walgreens NDC 0363-0652-06

Allergy Nasal Spray Fluticasone Propionate 50 mcg per spray

4 x 144 sprays

Allergy Symptom Reliever (Glucocorticoid)

24 Hour Relief of: Itchy, Watery Eyes Nasal Congestion Runny Nose Itchy Nose Sneezing

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



Principle Display Panel - Bottle (72ms)

BOTTLE LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

Walgreens NDC 0363-0652-05

Allergy Nasal Spray

Fluticasone Propionate 50 mcg per spray

72 sprays

Allergy Symptom Reliever

(Glucocorticoid)



Principle Display Panel - Carton (72ms)

CARTON LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

Walgreens NDC 0363-0652-03

Allergy Nasal Spray

Fluticasone Propionate 50 mcg per spray

72 sprays

Allergy Symptom Reliever

(Glucocorticoid)

24 Hour Relief of:

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

1-989 12



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

Drug Facts (continued)

- 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. (1-800-222-1222)

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

TAMPED 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

Drug Facts (continued)

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 toll free 1-800-706-5575, weekdays, 8:30am - 5:00pm Eastern Standard Time

What problems can Walgreens 24-Hour Allergy Nasal Spray help with?

Walgreens 24-Hour Allergy Nasal Spray helps relieve a broad range of uncomfortable nasal and eye symptoms like congestion and itchy eyes. • Nasal symptoms • Eye symptoms

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

- Outdoor allergens • Animal allergens • Indoor allergens



ACTUAL SIZE

ING2212-1
W3ORG0821-F

FULL PRESCRIPTION STRENGTH

NDC 0363-0652-03

Walgreens

Compare to the active ingredient in Flonase® Allergy Relief*

24 HOUR RELIEF

Allergy Nasal Spray

FLUTICASONE PROPIONATE 50 mcg PER SPRAY / ALLERGY SYMPTOM RELIEVER (GLUCOCORTICOID)*

24 Hour Non-Drowsy

- Relief of itchy, watery eyes, nasal congestion, runny nose, itchy nose & sneezing
- Allergy relief

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

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

- 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
- do not share this bottle with anyone else as this may spread germs



21536-1

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED

walgreens.com

©2021 Walgreen Co. MADE IN CANADA

ITEM 385895 W00000-0000-0



3 11917 03167 5



FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-0652 |
| 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: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0363-0652-01 | 1 in 1 CARTON | 02/02/2021 | |
| 1 | NDC:0363-0652-04 | 144 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) | | |
| 2 | NDC:0363-0652-02 | 2 in 1 CARTON | 02/02/2021 | |
| 2 | | 144 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) | | |
| 3 | NDC:0363-0652-06 | 4 in 1 CARTON | 02/26/2021 | |
| 3 | | 144 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) | | |
| 4 | NDC:0363-0652-03 | 1 in 1 CARTON | 02/02/2021 | |
| 4 | NDC:0363-0652-05 | 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 | 02/02/2021 | |

Labeler - Walgreens (008965063)

Registrant - Apotex Inc. (209429182)

Revised: 5/2023

Walgreens