FLUTICASONE PROPIONATE- fluticas one propionate spray, metered Walmart

## 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 $\bullet$ runny nose $\cdot$ sneezing $\bullet$ itchy nose


## 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 $4^{\circ}$ to $30^{\circ} \mathrm{C}\left(39^{\circ}\right.$ to $\left.86^{\circ} \mathrm{F}\right)$
- keep this label and enclosed materials. They contain important additional information.


## Inactive ingredients

$0.02 \% \mathrm{w} / \mathrm{w}$ benzalkonium chloride, dextrose, microcrystalline cellulose and carboxymethylcellulose sodium, $0.25 \% \mathrm{w} / \mathrm{w}$ phenylethyl alcohol, polysorbate 80 , purified water

## Questions or comments?

1-888-287-1915

Principal Display Panel - Carton (60md)
CARTON LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray
Walmart NDC 49035-060-01
Fluticas one Propionate Nas al Spray, USP
60 sprays

## Allergy Symptom Reliever Nas al Spray

## 24 Hour Relief of:

- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing


Principal Display Panel - Bottle (60md)
BOTTLE LABEL - PRINCIPAL DISPLAY PANEL - 50 mcg per spray

## Allergy Symptom Reliever Nas al Spray



## FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

## Product Information



FLUTICASO NE PRO PIO NATE (UNII: O2GMZ0LF5W) (Flutic a so ne - UNII:CUT2W21N7U) FLUTICASONE PROPIONATE 50 ug

## Inactive Ingredients

Ingredient Name
Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)
CARBO XYMETHYLCELLULO SE SO DIUM (UNII: K6 79 OBS311)
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D6 1U)
DEXTRO SE (UNII: IY9 XDZ35W2)
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)
POLYSORBATE 80 (UNII: 6OZP39 ZG8H)
WATER (UNII: 059 QF0 KO0R)

## Packaging

| \# | Item Code | Package Description |
| :--- | :--- | :--- |


| Marketing Category | Application Number or Monograph Citation | Marketing Start Date |
| :--- | :---: | :---: |
| ANDA | ANDA208150 | $06 / 10 / 2016$ |
|  |  |  |

## Labeler - Walmart (051957769)

Registrant - Apotex Inc. (209429182)

## Establishment

| Name | Address | ID/FEI |
| :---: | :---: | :---: |
| Apotex Inc. | 255092496 | analysis $(49035-060)$, manufacture $(49035-060)$ |

## Establishment

| Name | Address | ID/FEI | Business Operations |
| :---: | :---: | :---: | :---: |
| Legacy Pharmaceutical Packaging |  | 143213275 | pack(49035-060) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
| :---: | :---: | :---: | :---: |
| Jones Contract Packaging Services |  | 243697187 | pack $49035-060)$ |

