

**FLUTICASONE PROPIONATE- fluticasone propionate spray, metered**  
**Selder, S.A. de C.V.**

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**380 - XL-3 Nasal Spray**

**Active ingredient**

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**

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

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

- the growth 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 2 months a year.
- an adult should supervise use
- use 1 spray in each nostril 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° - 30°C (39° - 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 1-888-952-0050 weekdays

8:30am - 5:00pm Eastern Standard Time

## **Principal Display Panel**

XL-3\*

Allergy Cortix

FLUTICASONE PROPIONATE

NASAL SPRAY, USP

50 mcg Per Spray

Allergy Symptom Reliever

(Glucocorticoid

24 hour (icon) Non-Drowsy\*

relief of:

Itchy, watery eyes

Nasal congestion

Runny nose

Itchy nose

Sneezing

Full Prescription Strength

120 Metered Sprays

0.54 FL OZ (15.8mL)



**Fluticasone Propionate 50mcg**

**FLUTICASONE PROPIONATE**

fluticasone propionate spray, metered

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:63654-380 |
| <b>Route of Administration</b> | 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</b> (UNII: K679OBS311) |          |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)   |          |
| <b>DEXTROSE</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:63654-380-01 | 1 in 1 CARTON  | 05/17/2017           |                    |
| 1 |                  | 120 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                               | 05/17/2017           |                    |

**Labeler** - Selder, S.A. de C.V. (824413629)

Revised: 11/2017

Selder, S.A. de C.V.