# ALLERGY- loratadine tablet Selder, S.A. de C.V.

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309 - XL-3 Allergy

### **Active ingredient**

Loratadine 10mg

#### Purpose

Antihistamine

#### Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- sneezing
- runny nose
- itchy, watery eyes
- itching of the nose or throat.

#### Warnings

#### Do not use

if you have ever had an allergic reaction to this product or any of its ingredients

#### Ask a doctor before use

liver or kidney disease. Your doctor should determine if you need a different dose.

#### When using this product

do not take more than directed. Taking more than directed may cause drowsiness.

#### Stop use and ask a doctor

if an allergic reaction to this product occurs. Seek medical help right away.

#### Pregnancy/Breastfeeding

**If pregnant or breast-feeding,** ask a health professional before use.

#### Keep out of reach of children

**Keep out of reach of children.** In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately.

#### **Directions**

**Adults and children 6 years and over:** 1 tablet daily; not more than 1 tablet in 24 hours

**Children under 6 years of age:** ask a doctor

## Consumers with liver or kidney disease: ask a doctor

#### Other information

- store between 20° to 25°C (68° to 77° F)
- protect from excessive moisture
- do not use if blister packaging is torn or open

## **Inactive ingredients**

croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, silicon dioxide

## Questions or comments?

1-888-952-0050 Monday through Friday 9 AM - 5 PM EST

## **Principal Display Panel**



#### XL-3 Allergy Relief

#### **ALLERGY**

loratadine tablet

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63654-309
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		

Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	6 mm	
Flavor		Imprint Code	LOR;10;APO	
Contains				

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:63654-309-10	1 in 1 CARTON	12/16/2014	
1	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076471	12/16/20 14	

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

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