LORATADINE- loratadine tablet
DIRECT RX

LORATADINE

USES

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

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

ACTIVE INGREDIENT IN EACH TABLET

Loratadine 10 mg

PURPOSE

Antihistamine

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 if you have

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.

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.

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

- do not use if printed foil under cap is broken or missing
- store at 20°-25°C (68°-77°F)

Questions or comments?

1-800-719-9260

INACTIVE INGREDIENTS

Inactive ingredients

lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

KEEP OUT OF REACH OF CHILDREN

PRINCIPAL DISPLAY PANEL

Compare to Claritin® active ingredient

Loratadine Tablets, 10 mg

Antihistamine

24 Hour

Relief of:

Sneezing

Runny Nose

Itchy, Watery Eyes

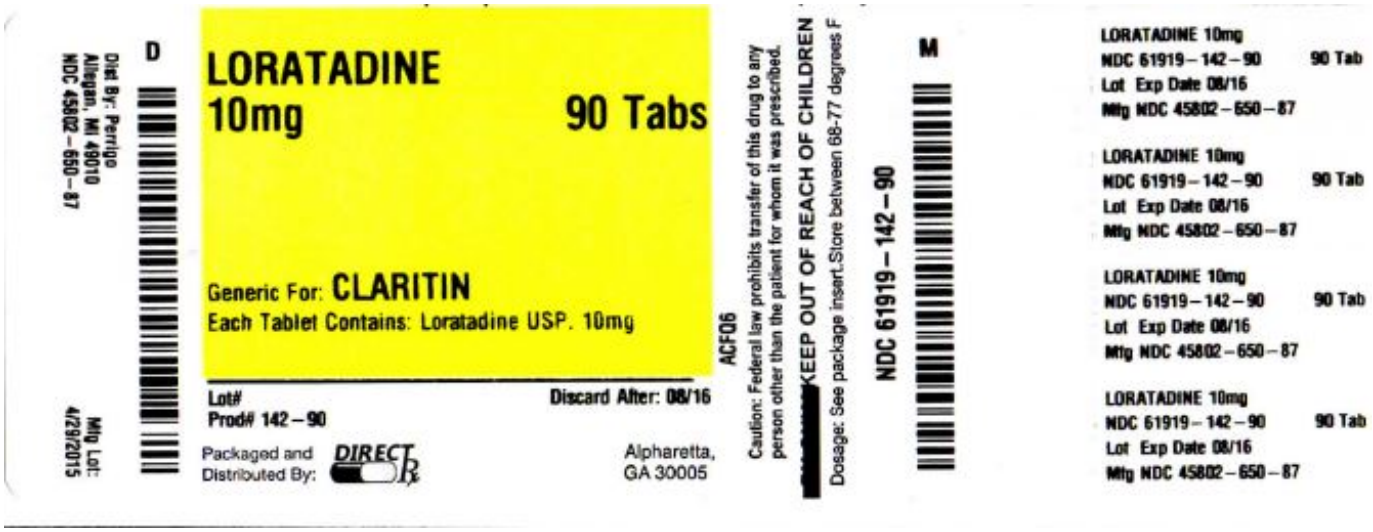
Itchy Throat or Nose

Indoor & Outdoor Allergies

Non-Drowsy*

*When taken as directed. See Drug Facts Panel.

10mg Label Image:



LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-142(NDC:45802-650)
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**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	L612
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-142-10	10 in 1 BOTTLE		
1	NDC:61919-142-30	30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:61919-142-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076301	01/01/2014	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-142) , relabel(61919-142)