LORATADINE- loratadine tablet
A-S Medication Solutions

NorthStar RxLLC Loratadine Tablets Drug Facts

Active ingredient (in each tablet)

Loratadine 10 mg

Purpose

Antihistamine

Uses

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

- runny nose
- itchy, watery eyes
- sneezing
- 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 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. (1-800-222-1222)

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

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

Inactive ingredients

lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

Questions or comments?

1-800-206-7821

HOW SUPPLIED

Product: 50090-4300

NDC: 50090-4300-0 10 TABLET in a BOTTLE

NDC: 50090-4300-1 20 TABLET in a BOTTLE

NDC: 50090-4300-3 15 TABLET in a BOTTLE

NDC: 50090-4300-4 30 TABLET in a BOTTLE

NDC: 50090-4300-5 90 TABLET in a BOTTLE

NDC: 50090-4300-6 7 TABLET in a BOTTLE

Loratadine

LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-4300(NDC:16714-898)
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, UNSPECIFIED (UNII: FZ989GH94E)	

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:50090-4300-3	15 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2019	
2	NDC:50090-4300-6	7 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2019	

3	NDC:50090-4300-0	10 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2019	
4	NDC:50090-4300-4	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2019	
5	NDC:50090-4300-5	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2019	
6	NDC:50090-4300-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076301	02/20/2019	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4300) , REPACK(50090-4300)

Revised: 1/2024 A-S Medication Solutions