LORATADINE- loratadine tablet A-S Medication Solutions

Drug Facts

Active Ingredient (in each tablet)

Loratadine, USP 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.

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

- Safety sealed: do not use if the imprinted bottle seal is open or torn (for bottle only).
- Safety sealed: do not use if open or torn (for blister package only).
- Store at 20° to 25°C (68° to 77°F) (see USP Controlled Room Temperature).

Inactive Ingredients

Lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

Questions or comments?

1-800-206-7821

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Manufactured for: Northstar Rx LLC

Memphis, TN 38141.

Manufactured by: Sandoz Inc.

Princeton, NJ 08540.

HOW SUPPLIED

Product: 50090-3464

NDC: 50090-3464-0 30 TABLET in a BOTTLE

Loratadine



LORATADINE

loratadine tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-3464(NDC:16714-482)	
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)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			

Product Characteristics			
Color	WHITE (white to off white)	Score	no score
Shape	ROUND	Size	6 mm
Flavor		Imprint Code	GG296
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:50090-3464-	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075209	02/01/2016	

Labeler - A-S Medication Solutions (830016429)

Establishment			
Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3464), REPACK(50090-3464)

Revised: 9/2018 A-S Medication Solutions