LORATADINE- loratadine tablet
A-S Medication Solutions

Loratadine Tablet 10 mg

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
- sneezing
- 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 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 induction seal, with "Lift N Peel" tab, under cap is broken or missing

- store between 2°C and 30°C (36°F and 86°F)
- protect from excessive moisture

Inactive ingredients

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

HOW SUPPLIED

Product: 50090-0838

NDC: 50090-0838-0 10 TABLET in a BOTTLE

NDC: 50090-0838-1 20 TABLET in a BOTTLE

NDC: 50090-0838-3 15 TABLET in a BOTTLE

NDC: 50090-0838-4 30 TABLET in a BOTTLE

NDC: 50090-0838-5 90 TABLET in a BOTTLE

NDC: 50090-0838-6 7 TABLET in a BOTTLE

Questions or comments?

Call **1-800-706-5575**, weekdays, 8:30 am - 5:00 pm Eastern Standard Time

Manufactured by:	Manufactured for:
Apotex Inc.	Apotex Corp.
Toronto, Ontario	Weston, Florida
Canada M9L 1T9	33326

Revised: August 2018

Loratadine

LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-0838(NDC:60505-0147)
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	LOR;10;APO
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50090-0838-5	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014	
2	NDC:50090-0838-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014	
3	NDC:50090-0838-3	15 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014	
4	NDC:50090-0838-6	7 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014	
5	NDC:50090-0838-0	10 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014	
6	NDC:50090-0838-4	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076471	01/24/2005	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-0838) , REPACK(50090-0838)

Revised: 1/2020 A-S Medication Solutions