

LORATADINE- loratadine tablet
Preferred Pharmaceuticals Inc

Loratadine

Drug Facts

Active Ingredient (in each tablet)

Loratadine, 10 mg USP

Purpose

Antihistamine

Uses

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

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

Warnings

Do not use if you ever have 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 of age 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

- Tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken.
- Store between 20° - 25°C (68°-77°F)

Inactive ingredients corn starch, lactose monohydrate, magnesium stearate, povidone

Questions or comments?

Call 1-800-874-7464 Monday to Friday 9 AM to 5 PM EST

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Container Label

<p>Loratadine Tablets 10mg</p> <p>Generic for Claritin</p> <p>Active ingredient (in each tablet) Loratadine 10mg.....Antihistamine</p> <p>Pkg Size: Exp Date: ##/##/#### Lot#: Batch#:</p> <p>Ins: Mfg: Unique Pharmaceutical Laboratories Prod#:</p> <p>Warning Store at 20°- 25°C (68°- 77°F). See USP Controlled Room Temperature. 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. 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. Keep this and all medication out of the reach of children. If pregnant or breast feeding, ask a health professional before use. Tablet is round, white, imprinted with 10 / P</p>		<p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed.</p>	<p>Loratadine Tablets 10mg Qty: Ins: Lot: Bat: Prod# (NDC):</p>	Log	
	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Directions English</p> <p>Use as directed by your doctor Take ___ tablet(s) every ___ hours.</p>	 <p>GTIN ##### SN ##### EXP #####</p>	<p>Instrucciones Espanol: Usó según lo dirigido por su doctor Toma ___ tableta(s) cada ___ horas.</p>	<p>Loratadine Tablets 10mg Qty: Ins: Lot: Bat: Prod# (NDC):</p>	Chart
			<p>Loratadine Tablets 10mg Qty: Insurance NDC: Lot: Bat:</p>	Billing	
			<p>Loratadine Tablets 10mg Qty: Ins: Lot: Bat: Prod# (NDC):</p>	Patient	

LORATADINE			
loratadine tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8616(NDC:16571-822)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	10 mg
Inactive Ingredients			
	Ingredient Name		Strength

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	white (white to off-white)	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	10;p
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8616-0	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2024	
2	NDC:68788-8616-1	14 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2024	
3	NDC:68788-8616-5	15 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2024	
4	NDC:68788-8616-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2024	
5	NDC:68788-8616-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2024	
6	NDC:68788-8616-8	10 in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214684	03/26/2024	

Labeler - Preferred Pharmaceuticals Inc (791119022)

Registrant - Preferred Pharmaceuticals Inc (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc		791119022	REPACK(68788-8616)