

LORATADINE ALLERGY RELIEF- loratadine tablet
PD-Rx Pharmaceuticals, Inc.

Loratadine Allergy Relief

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 (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	ask a doctor

age

ask a doctor

consumers with liver or kidney disease

ask a doctor

Other Information

- store between 20° to 25° C (68° to 77° F)
- protect from excessive moisture
- **TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE..**

Inactive ingredients

corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

Questions?

call **1-800-406-7984**

PRINCIPAL DISPLAY PANEL - 10 mg Tablet

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose Loratadine, USP 10 mgAntihistamine</p> <p>Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • itching of the nose or throat • runny nose • itchy, watery eyes • sneezing</p> <p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.</p> <p>When using this product do not take more than directed. Taking more than directed may cause drowsiness.</p> <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>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).</p>	<p>NDC 55289-728-90</p>  <p>24 Hour Allergy Relief</p> <p>Loratadine</p> <p>Tablets USP, 10mg</p> <p>Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc Oklahoma City, OK 73127 1-405-942-3040 V.8.19.0</p> <p>90 Tablets</p> <p>TAMPER EVIDENT. DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.</p>	 <p>GTIN: 00355289728900 SNO: C22B57000063 EXP: 12/2022 LOT: C22B57</p> <p>Drug Facts (Continued)</p> <table border="1"> <tr> <td>Directions</td> <td></td> </tr> <tr> <td>• adults and children 6 years and over</td> <td>1 tablet daily; not more than 1 tablet in 24 hours.</td> </tr> <tr> <td>• children under 6 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>• consumers with liver or kidney disease</td> <td>ask a doctor</td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> • store between 20° to 25°C (68° to 77°F) • Protect from excessive moisture <p>Inactive ingredients corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch</p> <p>Questions? call 1-800-406-7984 (mfg) OHM</p>	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
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									

LORATADINE ALLERGY RELIEF

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55289-728(NDC:51660-526)
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
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white (White to Off White)	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	RX526
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55289-728-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2020	
2	NDC:55289-728-15	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2021	
3	NDC:55289-728-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2021	
4	NDC:55289-728-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2018	
5	NDC:55289-728-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/18/2023	
6	NDC:55289-728-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076134	11/01/2017	

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(55289-728)

Revised: 3/2024

PD-Rx Pharmaceuticals, Inc.