

LORATADINE ANTIHISTAMINE- loratadine tablet
PD-Rx Pharmaceuticals, Inc.

Loratadine Tablets, 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
- 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?

1-800-719-9260

Principal Display Panel

Compare to Claritin[®] active ingredient

Loratadine Tablets, 10 mg

Antihistamine

24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

*When taken as directed. See Drug Facts Panel.

30 TABLETS, NDC 72789-347-30

90 TABLETS, NDC 72789-347-90

300 TABLETS, NDC 72789-347-87

Drug Facts	
Active ingredient (in each tablet)	Purpose
Loratadine 10 mg	Antihistamine
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	
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).	

NDC 72789-347-90



24 Hour Allergy Relief, Antihistamine

Loratadine

Tablets, 10mg

Marketed and Packaged By:
PD-Rx Pharmaceuticals, Inc
Oklahoma City, OK 73127
1-405-942-3040 v.8.19.0

90 Tablets
TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.

GTIN: 00372789347301
SNO: F23D75000004
EXP: 09/2024
LOT: F23D75

Drug Facts (Continued)	
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 • store between 20° to 25°C (68° to 77°F)	
Inactive ingredients lactose monohydrate, magnesium stearate, povidone, pregelatinized starch	
Questions or Comments? call 1-800-719-9260	

LORATADINE ANTIHISTAMINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72789-347(NDC:45802-650)
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)	

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:72789-347-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/23/2023	
2	NDC:72789-347-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/23/2023	
3	NDC:72789-347-87	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/23/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076301	10/15/2008	

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(72789-347)

Revised: 2/2024

PD-Rx Pharmaceuticals, Inc.