LORATADINE ALLERGY RELIEF- loratadine tablet Contract Pharmacy Services-PA

Drug Facts 452

ACTIVE INGREDIENT(S)

Loratadine USP, 10 mg

PURPOSE

Antihistamine

USE(S)

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 and kidney disease	ask a doctor

OTHER INFORMATION

- store between 20 and 25° C (68 and 77° F)
- protect from excessive moisture
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED 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



NDC 67046-452-30

 $^{\dagger}\text{Compare}$ to the active ingredient of <code>Claritin</code> $^{\texttt{®}}$

NON-DROWSY*

24 HourAllergy Relief

ohm®

Loratadine Tablets USP, 10 mg

Antihis tamine

Indoor & Outdoor Allergies

Relief of:

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

30 Tablets

When taken as directed. See Drug Facts Panel.

Manufactured by: Ohm Laboratories Inc.

5069178/0908

LORATADINE	E ALLERG	Y RELIEF					
Product Informa	tion						
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:67046-452	2(NDC:516	660-526)
Route of Administra	ition	ORAL					
A		- 4					
Active Ingredien		•					
Ingredient Name Basis of Stre					ength	Strength	
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN) LORATADINE					10 mg		
Inactive Ingredie	ents						
Ingredient Name					Strength		
STARCH, CORN (UNII: O8232NY3SJ)							
LACTOSE MONOHY	LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)						
MAGNESIUM STEAR	MAGNESIUM STEARATE (UNII: 70097M6I30)						
Product Characte	eristics						
Color	white (White to	Off White)		Score		no so	ore
Shape	ROUND			Size		6mm	
Flavor				Imprint Co	de	RX52	26
Contains							

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:67046-452-07	7 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017				
2	NDC:67046-452-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017				
3	NDC:67046-452- 60	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017				
4	NDC:67046-452-14	14 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017				
5	NDC:67046-452-15	15 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017				
6	NDC:67046-452-28	28 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017				
7	NDC:67046-452-21	21 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017				
Marketing Information							
Marketing Category		y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
	NDA	ANDA076134 (9/19/2017				

Labeler - Contract Pharmacy Services-PA (945429777)

Establishment

Name	Address	ID/FEI	Business Operations
Coupler Enterprises		945429777	repack(67046-452)

Revised: 12/2018

Contract Pharmacy Services-PA