LORATADINE- loratadine tablet
DRUG OCEAN LLC

Loratadine Tablets, 10 mg

Active ingredient

Loratadine 10 mg

Purpose

Antihistamine

Uses

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

- runny nose
- sneezing
- itchy, water 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 usung 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

- Tamper-evident: do not use if foil under cap is missing, open or broken
- store between 20º to 25ºC (68º to 77ºF)

Inactive ingredients

Lactose monohydrate, magnesium stearate, povidone, starch maize pregelatinized

Questions or comments?

1-844-200-6566 Monday to Friday 9 AM to 5 PM EST

Manufactured by:

Unique Pharmaceutical Laboratories

(A Div. of J. B. Chemicals & Pharmaceuticals Ltd.),

Mumbai 400 030, India.

Distributed by:

DRUG OCEAN

Drug Ocean LLC

1 Bridge Plaza, North Central Road,

6th Floor, Suite 675, Fort Lee, NJ 07024

DISPLAY PANEL

NON-DROWSY* 24 Hour

Loratadine Tablets, USP

Indoor and Outdoor Allergies

10mg

Relief of: • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy, Nose or Throat

*When taken as directed.

See Drug Facts Panel.

100 Tablets

LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70985-017
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**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	white (White to off white)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	P;10
Contains			

Packaging			
#	**Item Code**	**Package Description**	**Marketing Start**	**Marketing End**

#	Item Code	Package Description	Date	Date
1	NDC:70985-017-01	100 in 1 PACKAGE; Type 0: Not a Combination Product	06/27/2021	
2	NDC:70985-017-10	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/27/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214684	06/27/2021	

Labeler - DRUG OCEAN LLC (080381835)

Registrant - DRUG OCEAN LLC (080381835)

Establishment

Name	Address	ID/FEI	Business Operations
Unique Pharmaceutical Laboratories		650434645	manufacture(70985-017)

Revised: 10/2023 DRUG OCEAN LLC