

**LORATADINE- loratadine tablet
Granules India Limited**

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
- 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 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 seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken
- store between 20° to 25°C (68° to 77°F)

INACTIVE INGREDIENTS

Lactose monohydrate, magnesium stearate, sodium starch glycolate and starch maize pregelatinized

QUESTIONS OR COMMENTS

Contact 1-877-770-3183 Mon-Fri 9:00 AM to 4:30 PM EST

Loratadine Tablets USP 10 mg

Each tablet contains Loratadine USP 10 mg.

Batch No. : 7870001A

Mfg. Dt. : 01/2020

Exp. Dt. : 12/2022

Mfg.Lic.No. : 37/RR/AP/2003/F/R

NDC No. : 62207-787-88

Storage : Store between 20° to 25° C (68° to 77° F)

Caution :For repacking only.

No. of Units : 5 x 20000

Gross Wt. : 00.000 Kg

Tare Wt. : 00.000 Kg

Net Wt. : 00.000 Kg

Box No. : 000

Country of Origin: INDIA



(00)189038320000000004



(01)50362207787883(17)221200(10)7870001A

GIL/PL/041C



Manufactured by:

Granules India Limited

Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village,
Dundigal-Gandimaisamma Mandal, Medchal-Malkhajgiri District - 500043,
Telangana, INDIA

FG Code: 700000001316

Loratadine Tablets USP, 10 mg

Each tablet contains
Loratadine USP 10 mg.

Batch No. : XXXXXXXX

No. of Units : 1000

Mfg. Dt. : MM/YYYY

Exp. Dt. : MM/YYYY

Mfg.Lic.No.: 37/RR/AP/2003/F/R

NDC No. : 62207-787-49

Storage : Store between 20° to 25° C (68° to 77° F)

Caution : For repacking only.

Country of Origin: INDIA

GIL/PL/041C



Manufactured by:

Granules India Limited

Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village,
Dundigal-Gandimaisamma Mandal, Medchal-Malkhajiri District - 500043,
Telangana, INDIA

Product code:70000000XXXXX

LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-787
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-787-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/08/2020	
2	NDC:62207-787-88	5 in 1 BOX	03/16/2020	
2		20000 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210722	01/08/2020	

Labeler - Granules India Limited (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	analysis(62207-787) , manufacture(62207-787)

Revised: 2/2023

Granules India Limited