

**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. : 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 Tablets USP 10 mg

Each tablet contains Loratadine USP 10 mg.

Batch No. : XXXXXXXX

No. of Units : 5 x 20000

Mfg. Dt. : YYYY/MM

Gross Wt. : 00.000 Kg

Exp. Dt. : YYYY/MM

Tare Wt. : 00.000 Kg

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

Net Wt. : 00.000 Kg

NDC No. : 62207-787-88

Box No. : 000

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

Caution :For repacking only.

Country of Origin: INDIA



(00)189038320000000004



(01)50362207787883(17)YYMMDD(10)XXXXXXX

FG Code: 70000001316

**LORATADINE**

loratadine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62207-787
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	10 mg

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	

### Product Characteristics

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

### 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

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

**Labeler** - Granules India Limited (915000087)

**Establishment**

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

Revised: 8/2025

Granules India Limited