LORATADINE- loratadine tablet
Granules India Ltd

Loratadine Tablets, 10 mg

ACTIVE INGREDIENT(S)

Loratadine 10 mg

PURPOSE

Antihistamine

USE(S)

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 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.

PREGNANCY/BREASTFEEDING

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

Blister Foil Units

safety sealed: do not use if the individual blister unit is open or torn

STORAGE

store between 20° to 25°C (68° to 77°F)

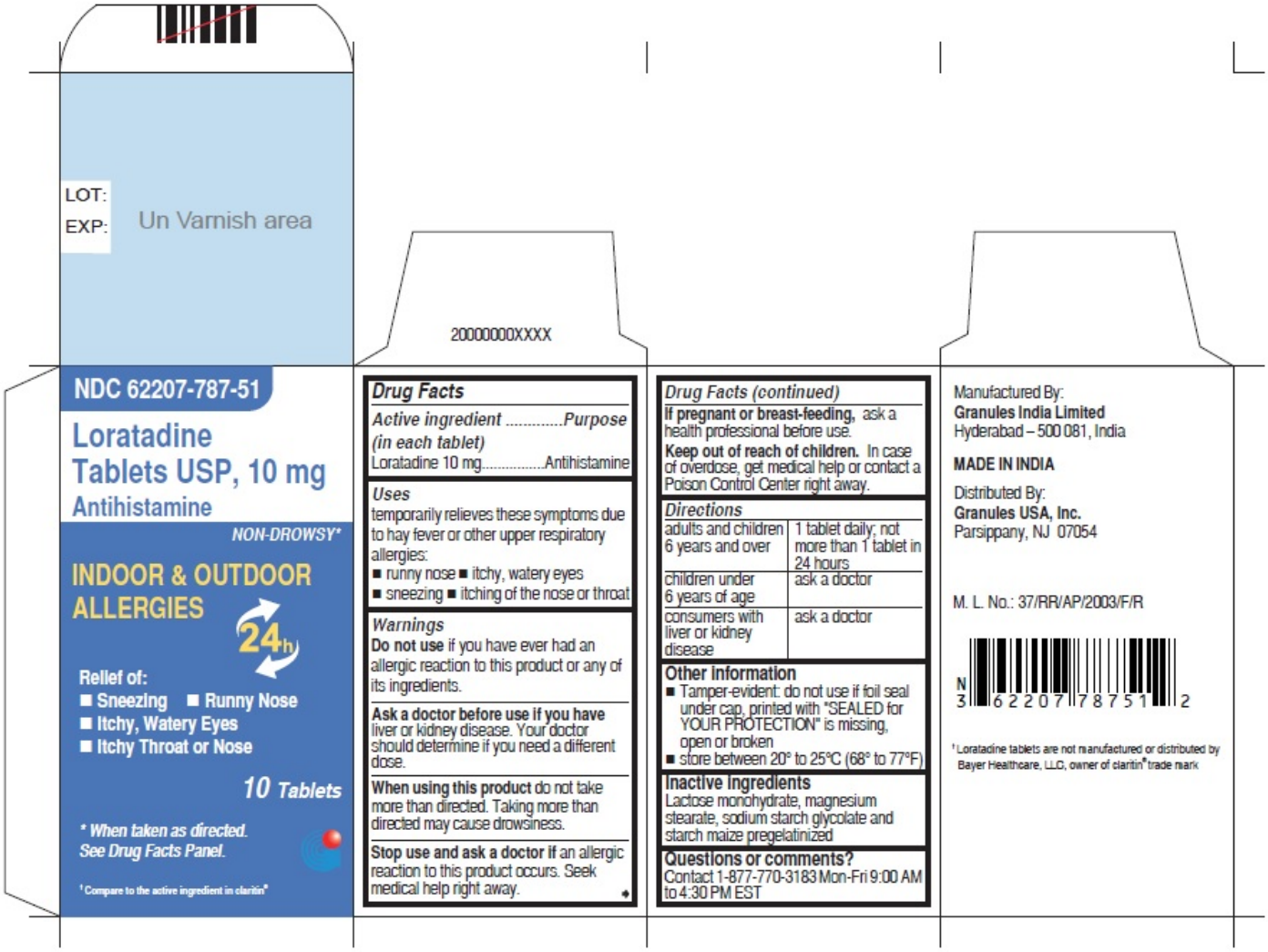
INACTIVE INGREDIENTS

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.

PRINCIPAL DISPLAY PANEL



LOT:
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NDC 62207-787-51

Loratadine Tablets USP, 10 mg

Antihistamine

*NON-DROWSY**

INDOOR & OUTDOOR ALLERGIES

24h

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

10 Tablets

* When taken as directed. See Drug Facts Panel.

† Compare to the active ingredient in claritin®

Drug Facts

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

Drug Facts (continued)

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

Manufactured By:
Granules India Limited
Hyderabad – 500 081, India

MADE IN INDIA

Distributed By:
Granules USA, Inc.
Parsippany, NJ 07054

M. L. No.: 37/RR/AP/2003/F/R

N 3 62207 78751 2

† Loratadine tablets are not manufactured or distributed by Bayer Healthcare, LLC, owner of claritin® trade mark

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: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg

Inactive Ingredients

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

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:62207-787-51	10 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	
2	NDC:62207-787-59	12 in 1 CARTON	01/01/2020	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

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

Labeler - Granules India Ltd (915000087)

Revised: 12/2019 Granules India Ltd