

**LORATADINE- loratadine tablet
GRANULES USA, INC.**

**Non-Drowsy
Allergy Relief
Loratadine Tablets, USP 10 mg
Antihistamine
Indoor and Outdoor Allergies
Relief of:
.Sneezing
.Runny Nose
.Itchy, Watery Eyes
.Itchy Throat or Nose**

Active ingredient (in each tablet)

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 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 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?

contact 1-877-770-3183: Mon-Fri 8:00AM EST to 5:00PM PST

Inside (adhesive side)

LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69848-019(NDC:62207-787)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03B07QN) (LORATADINE - UNII:7AJ03B07QN)	LORATADINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

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:69848-019-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210722	07/26/2021	

Labeler - GRANULES USA, INC. (137098864)

Revised: 1/2023

GRANULES USA, INC.