

**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

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

PDP

Inside (adhesive side)

LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69848-019
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
MAGNESIUM STEARATE (UNII: 70097M6130)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q815X)	

STARCH, CORN (UNII: O8232NY3SJ)

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: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)

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GRANULES USA, INC.