

SINULIEF- loratadine tablet
RoseWell Pharmaceuticals LLC

Active Ingredient (in each tablet)

Loratadine 10
mg.....Antihistamine

Drug Facts

Active Ingredient (in each tablet)

Purpose

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Active Ingredient (in each tablet)

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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.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) 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 ■ store between 20° to 25°C (68° to 77°F) ■ protect from excessive moisture
■ do not use if blister unit is torn or open ■ retain carton for complete product information.

Inactive ingredients lactose monohydrate, magnesium stearate, pregelatinized starch, sodium starch glycolate.

Questions and Comments? Call 1-833-999-7795.

†This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademark Claritin®.

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Package Label.Principal Display Panel



SINULIEF

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85510-101
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

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85510-101-01	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/18/2025	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/18/2025	

Labeler - RoseWell Pharmaceuticals LLC (119358987)