LORATADINE- loratadine tablet
AMZ789 LLC

Loratadine 10mg Tablets

Loratadine 10mg

Antihistamine

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.

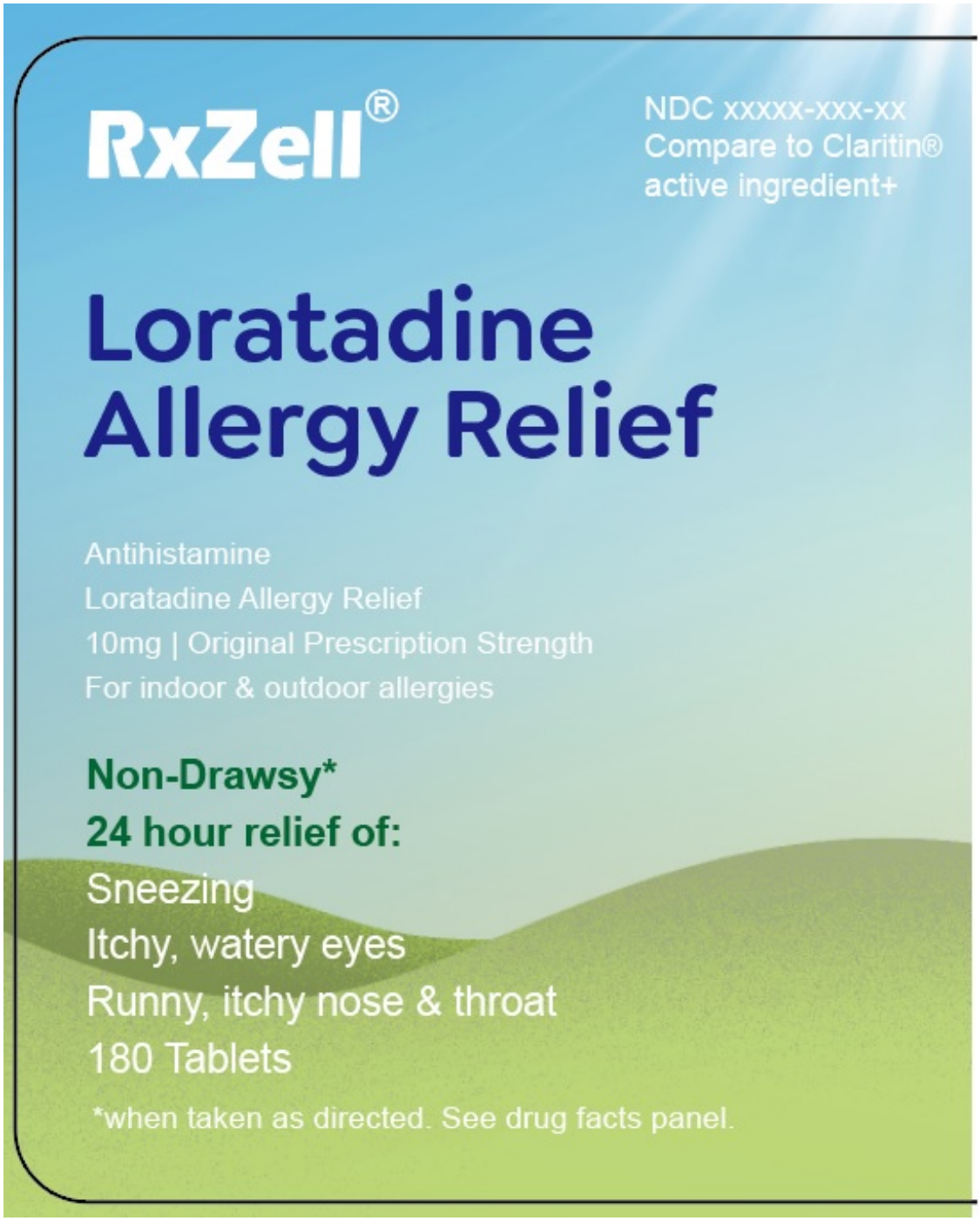
Adults and children 6 years and over 1 tablet daily: no more than 1 tablet in 24 hours

Children under 6 years of age ask a doctor

Consumers with liver or kidney disease ask a doctor

Other Information ● store between 20-25°C (68-77°F) ● protect from excessive moisture ● do not use if imprinted seal under safety cap is broken or missing

Inactive Ingredients lactose monohydrate, magnesium stearate, pregelatinized starch, sodium starch glycolate



LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73629-003
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73629-003-18	180 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210722	03/30/2022	

Labeler - AMZ789 LLC (117410213)

Establishment

Name	Address	ID/FEI	Business Operations
Nutra-Med Packaging Inc.		022004902	pack(73629-003)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	manufacture(73629-003)

Revised: 3/2022 AMZ789 LLC