LORATADINE - loratadine solution
Camber Consumer Care Inc

Loratadine Oral Solution USP, 5mg/5 mL (OTC)

ACTIVE INGREDIENT(S)

(in each 5 mL teaspoonful)
Loratadine USP, 5mg

PURPOSE

Antihistamine

USE(S)

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

•use only with enclosed dosing cup

adults and children 6 years and over	2 teaspoonfuls (tsp) daily; do not take more than 2 teaspoonfuls (tsp) in 24 hours
children 2 to under 6 years of age	1 teaspoonful (tsp) daily; do not take more than 1 teaspoonful (tsp) in 24 hours
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

OTHER INFORMATION

• Sodium Free
• do not use if tape imprinted with 'SEALED FORYOUR PROTECTION' on top and bottom flaps of carton is not intact
• store between 20° to 25°C (68° to 77°F)

INACTIVE INGREDIENTS

ART grape flavor, edetate disodium dihydrate, glycerin, maltitol solution, monobasic sodium phosphate, non crystallizing sorbitol solution, phosphoric acid, propylene glycol, purified water, sodium benzoate and sucralose

QUESTIONS OR COMMENTS?

Call **1-888-588-1418**

Distributed by:
Camber Consumer Care, Inc.
Piscataway, NJ 08854, USA.

STORAGE

PRINCIPAL DISPLAY PANEL

Loratadine Oral Solution USP, 5 mg/5mL 120 mL Carton Label

LORATADINE

loratadine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69230-322
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SORBITOL (UNII: 506T60A25R)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	yellow (colorless to yellow)	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69230-322-12	1 in 1 CARTON	05/07/2021	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69230-322-24	1 in 1 CARTON	05/07/2021	
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210409	05/07/2021	

Labeler - Camber Consumer Care Inc (079539968)

Establishment

Name	Address	ID/FEI	Business Operations
Hetero Labs Limited Unit III		676162024	analysis(69230-322) , manufacture(69230-322)

Revised: 5/2021 Camber Consumer Care Inc