LORATADINE - loratadine oral solution
KROGER COMPANY

Loratadine Oral Solution USP 5 mg/5 mL

Drug Facts

Active ingredient (in each 5 mL teaspoonful)

Loratadine USP 5 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- 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 (1-800-222-1222) 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

- **each teaspoonful contains**: sodium 6 mg
- do not use if carton is opened, or if cap safety seal is broken or missing.
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

artificial flavors, ascorbic acid, glycerin, maltitol, monobasic sodium phosphate monohydrate, phosphoric acid, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sorbitol, sucralose.

Questions or comments?

1-800-632-6900

DISTRIBUTRD BY THE KROGER CO.
CINCINNATI, OHIO 45202
MADE IN INDIA

Code:TS/DRUGS/19/1993

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 5 mg/5 mL (120 mL Bottle)

NDC 30142-062-24
Kroger®
Ages 2 Years & Older

children's
Allergy Relief

Loratadine Oral
Solution USP,
5 mg/5 mL

Antihistamine
INDOOR & OUTDOOR
ALLERGIES

24 HOUR
DYE-FREE
Grape Flavor

4 FL OZ (120 mL)

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 5 mg/5 mL Carton (120 mL)

COMPARE TO the active ingredient of
CHILDRENS'S CLARITIN® **See side panel
NDC 30142-062-24

Kroger®
Ages 2 Years & Older
Non-Drowsy*
children's
Allergy Relief
Loratadine Oral
Solution USP, 5 mg/5 mL
Antihistamine
INDOOR & OUTDOOR ALLERGIES
24 HOUR RELIEF OF:

Sneezing; Runny Nose;
Itchy,watery Eyes &
Itchy Throat or Nose

Contains sodium metabisulfite,
a sulfite that may cause
allergic-type reactions.

Dosing
Cup Included

DYE-FREE
Grape Flavor

4 FL OZ (120 mL)

*** When taken as directed.**

See Drug Facts Panel.

LORATADINE

loratadine oral solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30142-062
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
GRAPE (UNII: 6X543N684K)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-062-24	1 in 1 CARTON	03/15/2021	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208931	03/15/2021	

Labeler - KROGER COMPANY (006999528)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(30142-062) , MANUFACTURE(30142-062)

Revised: 4/2021 KROGER COMPANY