CHILDRENS LORATADINE- loratadine solution
Aidarex Pharmaceuticals LLC

Childrens Loratadine

Drug Facts

Active ingredient (in each 5 mL)

Loratadine 5 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

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.
- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.

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

Other information

- **safety sealed: do not use if imprinted safety seal is torn or missing**
- store between 2° and 25°C (36° and 77°F)

Inactive ingredients

artificial grape flavor, citric acid monohydrate, glycerin, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sucrose

Distributed by:
Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532

Repackaged By:
Aidarex Pharmaceuticals, LLC.
Corona, CA 92880

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 33261-908-01

Compare to the
active ingredient
in Claritin®*

GRAPE
FLAVOR

Original
Prescription Strength

Ages two years and older

Children's
Loratadine
Syrup
(Loratadine
Oral Solution)
5 mg/5 mL
Antihistamine

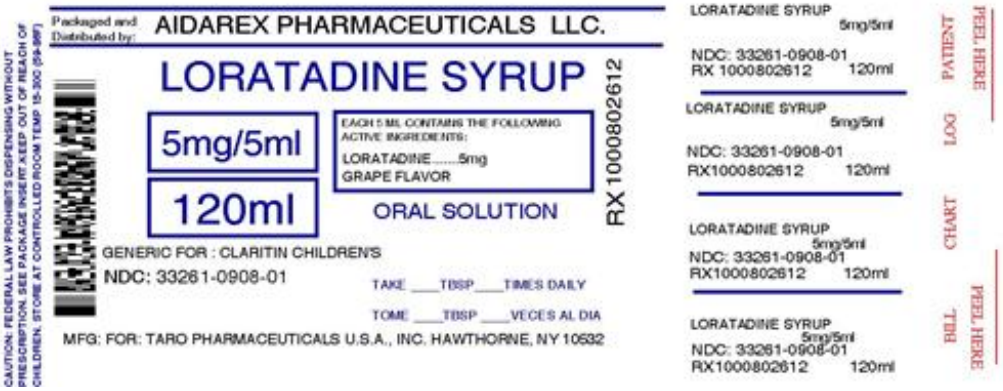
Grape Flavored Syrup

24 hour
Non-Drowsy†
Allergy Relief

Relief of:
Sneezing; Runny Nose,
Itchy, Watery Eyes,
Itchy Throat or Nose

4 FL OZ (120 mL)

† When taken as directed. See Drug Facts Panel.



CHILDRENS LORATADINE

loratadine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:33261-908(NDC:51672-2085)
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**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SUCROSE (UNII: C151H8M554)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:33261-908-01	5 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076805	08/20/2004	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 9/2012 Aidarex Pharmaceuticals LLC