CHILDRENS ALLERGY RELIEF- loratadine solution CVS Pharmacy

Children's Allergy Relief

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: CVS Pharmacy, Inc., Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

CVS[®] pharmacy

Compare to the active ingredient in Children's Claritin®†

Ages two years and older

CVS PHARMACIST RECOMMENDED

CHILDREN'S ALLERGY RELIEF

LORATADINE ORAL SOLUTION 5mg/5ml ANTIHISTAMINE

GRAPE FLAVORED SYRUP

24 hour Non-Drowsy* Allergy

Relief of:

Sneezing, Runny Nose, Itchy, Watery Eyes, Itchy throat or Nose

Dye free

* When taken as directed. See Drug Facts Panel.

4 FL OZ (120 mL)



SEALED WITH PRINTED NECKBAND

Drug Facts

Active ingredient (in each 5 mL) Loratadine 5 mg.

Purpose Anthistamine

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 orkichey 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 albigic 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 hefore use

Keep out of reach of children. In case of overdose, get medical help or contacta Poison Control Center right away.

Directions

adults and children 2 teaspoonfuls daily; do not take 6 years and over more than 2 teaspoonfuls in 24 hours 1 teaspoonful daily; do not take more than 1 teaspoonful in 24 hours children 2 to under 6 years of age

consumers with liver ask a doctor or kidney disease

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



Compare to the active ingredient in Children's Claritinet





CHILDREN'S

LORATADINE OR AL SOLUTION 5mg/5ml **ANTIHISTAMINE**

24 hour Non-Drowsy*

Relief of: Runny Nose, Itchy, Watery Eyes, Itchy throat or Nose



Dye free

* When taken as directed. See Drug Facts Panel.

4 FL OZ (120 mL)



CHILDREN'S

LORATADINE ORAL SOLUTION 5mg/5ml ANTIHISTAMINE

GRAPE FLAVORED SYRUP

24 hour Non-Drowsy* Allergy

- 24 Hour Relief
- · Alcohol-Free
- Grape Flavored
- Dosage Cup Enclosed



†This product is not manufactured or distributed by Schering-Plough Health Care Products Incowner of the registered trademark Claritin®.

Distributed by: CVS Pharmacy, Inc., Woonsocket, RI 02995 © 2008 CVS/pharmacy www.cvs.com Mede in Israel



* When taken as directed. See Drug Facts Panel.

4 FL OZ (120 mL)



Compare to the active ingredient in Children's Claritin®†

Ages two years and older



CHILDREN'S

LORATADINE ORAL SOLUTION 5mg/5ml ANTIHISTAMINE

24 hour Non-Drowsy*

Relief of: Runny Nose, Itchy, Watery Eyes, Itchy throat or Nose



* When taken as directed. See Drug Facts Panel.

4 FL OZ (120 mL)



70459-0808-1 486

CHILDRENS ALLERGY RELIEF

loratadine solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-446

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			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59779-446-04	1 in 1 CARTON			
1		60 mL in 1 BOTTLE			
2	NDC:59779-446-08	1 in 1 CARTON			
2		120 mL in 1 BOTTLE			
3	NDC:59779-446-01	1 in 1 CARTON			
3		240 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 - CVS Pharmacy (062312574)

Registrant - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment					
Name	Address	ID/FEI	Business Operations		
Taro Pharmaceutical Indutries Ltd.		600072078	MANUFACTURE(59779-446)		

Revised: 11/2012 CVS Pharmacy