WESTERN FAMILY CHILDRENS ALLERGY RELIEF- loratadine solution Western Family Foods Inc

Western Family® Children's Allergy Relief

Drug Facts

Active ingredient (in each 5 mL teaspoonful)

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.

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. (1-800-222-1222)

Directions

use only with enclosed dosing cup

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

Other information

- safety sealed: do not use if imprinted safety seal is torn or missing
- store between 20° and 25°C (68° and 77°F)

Inactive ingredients

glycerin, grape flavor, maltitol solution, masking agent, noncrystallizing sorbitol solution, phosphoric acid, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sodium phosphate monobasic dihydrate, sucralose powder.

Questions?

Call 1-866-923-4914

Proudly Distributed by **Western Family Foods, Inc.** P.O. Box 4057, Portland, OR 97208 U.S.A.

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

WESTERN FAMILY®

INDOOR & OUTDOOR ALLERGIES

Children's

Allergy

RELIEF

24 HOUR

Non-Drowsy[†]

LORATADINE

ORAL SOLUTION 5 mg/5 mL

Antihis tamine

2 years

and older

sugar free

Grape

flavored

syrup

24 HOUR RELIEF OF:

ISNEEZING

IRUNNY NOSE

IITCHY, WATERY EYES

IITCHY THROAT OR NOSE

4 FL OZ (120 mL)

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S CLARITIN®*

[†]When taken as directed. See Drug Facts Panel.







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Drug Facts

Active ingredient (in each 5 mL teaspoonful)

oratadine 5 mg....

Uses temporarily relieves these symptoms due to hay

Purpose

fever or other upper respiratory dergies:

• 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. (1-800-222-1222)

Directions

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use only with enclosed dosing cup
adults and children

2 teaspoonfuls (tsp) daily; do not take
more than 2 teaspoonfuls (tsp) in
24 hours

1 teaspoonful (tsp) daily; do not take more than 1 teaspoonful (tsp) in 24 hours 6 years of age

2 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 20° and 25°C (68° and 77

Inactive ingredients glycerin, grape flavor, maltitol solution, masking agent, noncrystallizing sorbitol solution, phosphoric acid, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, odium phosphate monobasic dihydrate, sucratose powder Questions? Call 1-866-923-4914

*This product is not manufactured or distributed by MSD Consumer Care Inc., a subsidary of Merck & Co., Inc.



24 HOUR RELIEF OF: Grape SNEEZING flavored syrup RUNNY NOSE ITCHY, WATERY EYES ITCHY THROAT OR NOSE

4 FL OZ (120 mL)

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S CLARITIN® .

RATADINE ORAL SOLUTION 5 mg / 5 mL Antihistamine Alcohol Free Sugar Free 24 Hour Relief Dosage Cup Enclosed

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WESTERN FAMILY CHILDRENS ALLERGY RELIEF

loratadine solution

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HUMAN OTC DRUG Product Type Item Code (Source)

ORAL Route of Administration

NDC:55312-092

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Loratadine (UNII: 7AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN) Loratadine (UNII: 7AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN)

Inactive Ingredients	
Ingredient Name	Strength
glycerin (UNII: PDC6A3C0OX)	
sorbitol (UNII: 506T60A25R)	
phosphoric acid (UNII: E4GA8884NN)	
polyethylene glycols (UNII: 3WJQ0SDW1A)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
sodium phosphate, monobasic, dihydrate (UNII: 5QWK665956)	

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

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-092-08	1 in 1 CARTON		
1		120 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA076805	02/27/2010		

Labeler - Western Family Foods Inc (192166072)

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

Establishment					
Name	Address	ID/FEI	Business Operations		
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(55312-092)		