SIMPLY RIGHT CHILDRENS CETIRIZINE- cetirizine hydrochloride solution
Sam's West Inc

SIMPLY RIGHT™
children's cetirizine

Drug Facts

Active ingredient (in each 5 mL teaspoonful)

Cetirizine HCl 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 or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

When using this product
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding:
- if breast-feeding: not recommended
- if pregnant: 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 years and over	1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours.
adults 65 years and older	1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) in 24 hours.
children 2 to under 6 years of age	½ teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or ½ teaspoonful (2.5 mL) every 12 hours. Do not give more than 1 teaspoonful (5 mL) in 24 hours.
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

artificial grape flavor, glacial acetic acid, glycerin, methylparaben, natural and artificial banana flavor, propylene glycol, propylparaben, purified water, sodium acetate (anhydrous), sucralose

Questions?

Call **1-866-923-4914**

Distributed by:
SAM'S West, Inc.
Bentonville, AR 72716

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

TWIN PACK

NDC 68196-102-02
24 hour relief

SIMPLY RIGHT™
Health Care

Original prescription strength

children's
cetirizine
hydrochloride
oral solution 1 mg/mL

antihistamine

Compare to Children's Zyrtec®
active ingredient*

allergy

24 hour relief of:

sneezing; runny nose;
itchy, watery eyes;
itchy throat or nose

indoor &
outdoor
allergies

2 yrs. & older

grape flavor

4 FL OZ (120 mL)
Dosing cup included

24 hour relief

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LABORATORY TESTED* QUALITY ASSURED

THE SIMPLY RIGHT™ PROMISE

Simply Right is dedicated to providing healthful, gentle, and safe personal care products for the entire family. We continuously strive to be your trusted partner in wellness and exceed your expectations.

We would like to hear from you with any comments or suggestions. In the continental US or Canada, you can call us toll-free at 1-800-809-0469, Monday through Friday, from 8 am to 5 pm CST. Or you can send us an email at samsclub.com.

Made in Israel.

0 78742 01248 3

LOT NO.

EXP.

:A4590 ZX C1

20223-0312-0
650

24 hour relief

SIMPLY RIGHT™
Health Care

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hydrochloride
oral solution 1 mg/mL

antihistamine

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children's cetirizine

hydrochloride
oral solution 1 mg/mL

antihistamine

Compare to Children's Zyrtec® active ingredient*

allergy

sugar free
alcohol free
dye free

Distributed by:
SAM'S West, Inc.
Bentonville, AR 72716

*This product is not manufactured or distributed by UCB Pharma, S.A. CORPORATION BELGIUM, owner of the registered trademark Children's Zyrtec®.

Dosing cup should be washed and left to air dry after each use.

Do not use if carton is opened, or if imprinted safety seal is broken or missing. See bottom panel for expiration date.

SIMPLY RIGHT CHILDRENS CETIRIZINE

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:68196-102
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetirizine Hydrochloride (Cetirizine)	Cetirizine Hydrochloride	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
acetic acid	
glycerin	
methylparaben	
propylene glycol	
propylparaben	
water	
sodium acetate anhydrous	
sucralose	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-102-02	2 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	ANDA090182	09/08/2011	

Labeler - Sam's West Inc (051957769)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(68196-102)