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

SIMPLY RIGHT™ children's cetirizine

Drug Facts

Active ingredient (in each 5 mL)

Cetirizine HCl 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 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
- find right dose on chart below
- mL = milliliter

5 mL or 10 mL once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours.
5 mL once daily; do not take more than 5 mL in 24 hours.
2.5 mL once daily. If needed, dose can be increased to a maximum of 5 mL once daily or 2.5 mL every 12 hours. Do not give more than 5 mL in 24 hours.
ask a doctor
ask a doctor

Other information

- do not use if carton is opened or if imprinted safety seal is broken or missing
- see bottom panel for lot number and expiration date
- 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 - 2 x 240 mL Bottle Carton

Twin Pack – 2 X 8 FL OZ

Compare to Children's Zyrtec[®] active ingredient*

NDC 68196-102-07

Member's Mark™

24 hour relief

original prescription strength

children's cetirizine

hydrochloride oral solution 1 mg/mL antihistamine allergy

24 hour relief of:

• Sneezing; runny nose; itchy, watery eyes; itchy throat or nose

- Indoor & outdoor allergies
- Sugar free Dye free
- 2 years and older

Grape flavor Dosing cup included

Contains 2 bottles of 8 FL OZ (240 mL) each/total 16 FL OZ (480mL)

Compare to Children's Zyrtec active ingredient

Member's Mark 24 hour relief

original prescription strength

children's cetirizi hydrochloride oral solution 1 mg/mL

antihistamine allergy

Twin Pack – 2 X 8 FL OZ

Compare to Children's Zyrtec active ingredient

NDC 68196-102-07

Member's Mark 24 hour relief

original prescription strength

children's cetirizine

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LOT NO.

Grape flavor

Dosing cup included



Compare to Children's Zyrtec active ingredient

> original prescription strength

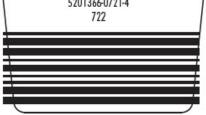
children's cetirizine

hvdrochloride oral solution 1 mg/mL antihistamine allergy

> Sugar free Dye free

*This product is not manufactured or distributed by UCB Pharma, S.A. CORPORATION BELGIUM, owner of the registered trademark Children's Zyrtec®, Dosing cup ould be washed and left to air dry after each us

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EXP.

Compare to Children's Zyrtec active ingredient



24 hour rellef

original prescription strength children's

cetirizine hydrochloride

> oral solution 1 mg/mL antihistamine allergy

> > Sugar free Dye free

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

SEALED WITH PRINTED NECKBAND

Drug Facts Active ingredient Purpose (in each 5 mL) Cetirizine HCl 5 mg. 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 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 occu 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)

> DISTRIBUTED BY: SAM'S WEST, INC. BENTONVILLE, AR 72716





Drug Facts (continued)

use only with enclosed dosing cup

5 mL or 10 mL once daily

depending upon severity

of symptoms; do not take

5 mL once daily; do not

take more than 5 mL in

2.5 mL once daily. If

needed, dose can be

increased to a maximum

of 5 mL once daily or 2.5 mL every 12 hours. Do not

give more than 5 mL in

more than 10 mL in

24 hours.

24 hours.

24 hours.

ask a doctor

ask a doctor

גובה דיצ לטובת הדבהה

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find right dose on chart below

Directions

mL = milliliter adults and children

6 years and over

adults 65 years

children 2 to under

6 years of age

children under

2 years of age

missing

expiration date

consumers with liver

Other information

do not use if carton is opened or if imprinted safety seal is broken or

see bottom panel for lot number and

Inactive ingredients

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

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

or kidney disease

and over

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SIMPLY RIGHT CHILDRENS CETIRIZINE cetirizine hydrochloride solution **Product Information** HUMAN OTC DRUG NDC:68196-102 **Product Type** Item Code (Source) ORAL **Route of Administration Active Ingredient/Active Moiety Basis of Strength** Strength Ingredient Name Cetirizine Hydrochloride (UNII: 640047KTOA) (Cetirizine - UNII:Y07261ME24) Cetirizine Hydrochloride 5 mg in 5 mL **Inactive Ingredients Ingredient Name** Strength acetic acid (UNII: Q40Q9N063P) glycerin (UNII: PDC6A3C0OX) methylparaben (UNII: A2I8C7HI9T) propylene glycol (UNII: 6DC9Q167V3) propylparaben (UNII: Z8IX2SC10H) water (UNII: 059QF0KO0R) sodium acetate anhydrous (UNII: NVG71ZZ7P0) sucralose (UNII: 96K6UQ3ZD4) **Product Characteristics** YELLOW (colorless to slightly yellow) Color Score Size Shape Flavor GRAPE (sugar free) **Imprint Code** Contains Packaging Marketing Start Marketing End **Item Code Package Description** # Date Date 1 NDC:68196-102- 2 in 1 CARTON 09/08/2011 02 120 mL in 1 BOTTLE; Type 0: Not a Combination 1 Product **2** NDC:68196-102- 2 in 1 CARTON 09/08/2011 01 240 mL in 1 BOTTLE; Type 0: Not a Combination 2 Product **3** NDC:68196-102- 2 in 1 CARTON 09/08/2011

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3	240 mL in 1 BOTTLE; Type 0: Not a Combination Product					
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)			

Revised: 7/2021

Sam's West Inc