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 useif 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 haveliver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you aretaking 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 ifan 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

Compare to Children's Zyrtec active ingredient

Twin Pack - 2 X 8 FL OZ

Compare to Children's Zyrtec active ingredient



Member's Mark

24 hour rellef

original prescription strength

children's cetirizine

hydrochloride 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 lould be washed and left to air dry after each us

Member's Mark 24 hour relief

NDC 68196-102-07

original prescription strength

children's cetirizine

hydrochloride oral solution 1 mg/mL antihistamine allergy



ভিন্ত্ৰেচ্ছ flavor Dosing sup included 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

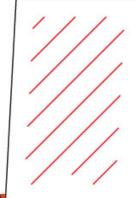
Contains 2 bottles of 8 FL OZ (240 mL) each/total 16 FL OZ (480mL)

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LOT NO.

EXP.



Compare to Children's Zyrtec active ingredient



Member's Mark...

24 hour relief

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hydrochloride oral solution 1 mg/mL antihistamine allergy

Sugar free
Dye free

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Uses

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- 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)

Drug Facts (continued)

Directions

- · use only with enclosed dosing cup
- · find right dose on chart below
- · mL = milliliter

adults and children 6 years and over	5 mL or 10 mL once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours.
adults 65 years and over	5 mL once daily; do not take more than 5 mL in 24 hours.
children 2 to under 6 years of age	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 no give more than 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

- 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

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SIMPLY RIGHT CHILDRENS CETIRIZINE

cetirizine hydrochloride solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68196-102

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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	CETIRIZ INE 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: Z8IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			
SODIUM ACETATE ANHYDROUS (UNII: NVG71ZZ7P0)			
SUCRALOSE (UNII: 96K6U03ZD4)			

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	09/08/2011	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68196-102- 01	2 in 1 CARTON	09/08/2011	06/24/2024
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		
_	NDC:68196-102-	2 := 1 CARTON	00/00/2011	

3 07	Z III I CARTON	09/00/2011		
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	ANDA000102	09/08/2011		
711071	ANDA090182	09/06/2011		

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: 6/2024 Sam's West Inc