UP AND UP CHILDRENS ALL DAY ALLERGY RELIEF- cetirizine hydrochloride solution Target Corporation

up&up children's all day allergy relief

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

- do not use if carton is opened, or if imprinted safety seal is broken or missing.
- see bottom panel for expiration date
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

bubble gum artificial flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate anhydrous, sucralose

Questions?

Call 1-866-923-4914

Distributed by Target Corp., Mpls., MN 55403

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 11673-106-08

children's all day allergy relief

cetirizine hydrochloride oral solution 1 mg/mL

antihis tamine

Compare to active ingredient in Children's Zyrtec®*

24 hour relief of: sneezing/itchy, watery eyes/runny nose/itchy throat or nose

indoor and outdoor allergies dye and sugar free dosing cup included

up&up

BUBBLEGUM FLAVOR

AGE

2+

YEARS

4 FL OZ (120 mL)

children's all day allergy relief

cetirizine hydrochloride oral solution 1 mg/mL antihistamine



children's all day allergy relief

cetirizine hydrochloride oral solution 1 mg/mL antihistamine NDC 11673-106-08

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upaup



50513-0613-0



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

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

094 04 0097 ID463427 Distributed by Target Corp., Mpls., MN 55403 Made in Israel

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Drug Facts (continued)

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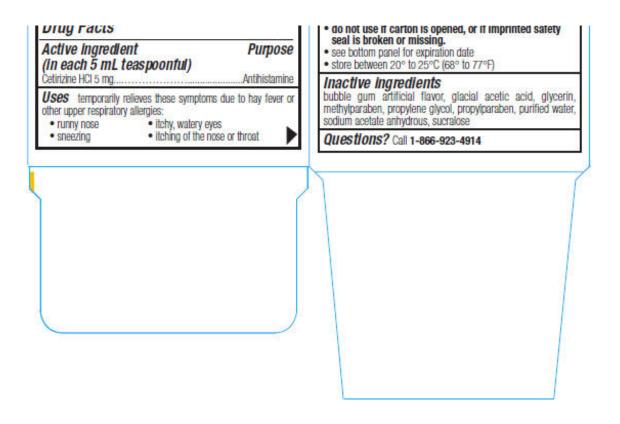
If pregnant or breast-feeding:

Other information

- . if breast-feeding: not recommended
- · if pregnant: ask a health professional before use.

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UP AND UP CHILDRENS ALL DAY ALLERGY RELIEF

cetirizine hydrochloride solution

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11673-106 |
| Poute of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|--------------------------|--------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| Cetirizine Hydrochloride (UNII: 640047KTOA) (Cetirizine - UNII:YO7261ME24) | Cetirizine Hydrochloride | 1 mg in 1 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: 96K6UQ3ZD4) | |

| Product Characteristics | | | |
|-------------------------|---------------------------------------|-------|--|
| Color | YELLOW (colorless to slightly yellow) | Score | |

| Shape | | Size |
|----------|-------------------------|--------------|
| Flavor | BUBBLE GUM (Sugar Free) | Imprint Code |
| Contains | | |

| P | ackaging | | | |
|---|------------------|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:11673-106-08 | 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 | ANDA201546 | 05/20/2011 | |
| | | | |

Labeler - Target Corporation (006961700)

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

| Establishment | | | | |
|--------------------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Taro Pharmaceutical Industries, Ltd. | | 600072078 | MANUFACTURE(11673-106) | |

Revised: 6/2013 Target Corporation