**SUNMARK CHILDRENS CETIRIZINE- cetirizine hydrochloride solution**
**McKesson**

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**sunmark®**
**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

| | |
|---|---|
| | 1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once |

| | |
|---|---|
| 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**

**Another Quality Product Distributed by McKesson**
**One Post Street, San Francisco, CA 94104**

**PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton**

**sunmark®**

COMPARE TO
CHILDREN'S ZYRTEC®
ACTIVE INGREDIENT*

NDC 49348-326-34

**Children's**
**all day**
**allergy**

**Cetirizine Hydrochloride**
**Oral Solution 1 mg/mL**
**Antihistamine**

**2 years & older**
**Indoor & outdoor allergies**

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

**Dosing Cup Included**

**SUGAR FREE**
**GRAPE FLAVOR**

**4 FL OZ (120 mL)**

sunmark®

Children's

# all day allergy

Cetirizine Hydrochloride
Oral Solution 1 mg/mL
Antihistamine

sunmark®

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4 FL OZ (120 mL)

4 FL OZ (120 mL)

4 FL OZ (120 mL)

NO COPY ON THIS FLAP
FOR LOT # AND EXPIRY
DATE PRINT

T181B


NO VARNISH
ON THIS FLAP

sunmark®

# Children's all day allergy

## Cetirizine Hydrochloride Oral Solution 1 mg/mL Antihistamine

**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.**

***This product is not manufactured or distributed by UCB Pharma, S.A. CORPORATION BELGIUM, owner of the**

## *Drug Facts* (continued)

### *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.

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

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### *Directions*

- use only with enclosed dosing cup

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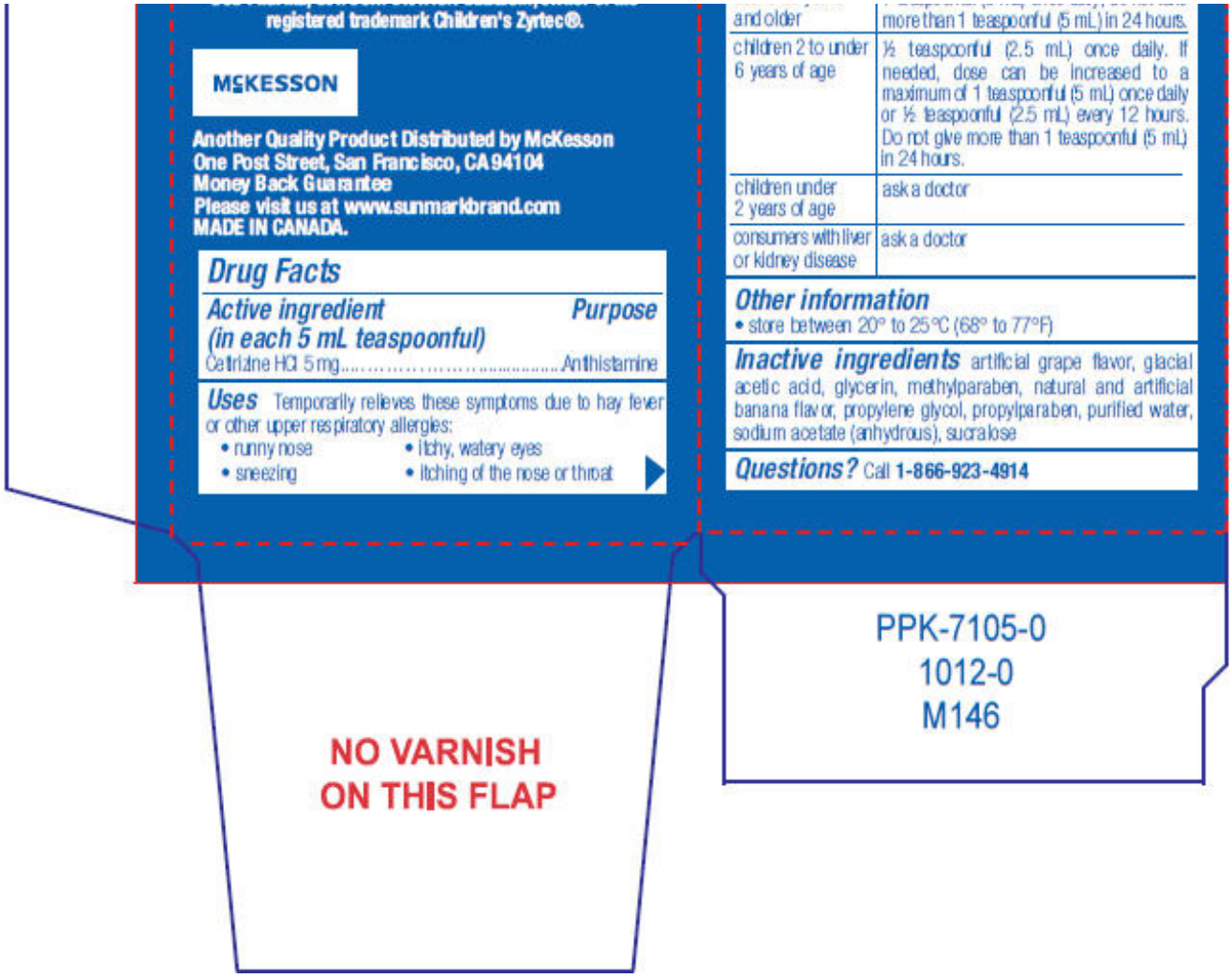
|---|---|
| adults and children 6 years and over | 1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours. |
| adults 65 years | 1 teaspoonful (5 mL) once daily; do not take |




# SUNMARK CHILDRENS CETIRIZINE

cetirizine hydrochloride solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:49348-326 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **Cetirizine Hydrochloride** (UNII: 64O047KTOA) (Cetirizine - UNII:YO7261ME24) | 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: Z8IX2SC1OH) | |

| | |
|---|---|
| **water** (UNII: 059QF0KO0R) | |
| **sodium acetate anhydrous** (UNII: NVG71ZZ7P0) | |
| **sucralose** (UNII: 96K6UQ3ZD4) | |

## 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:49348-326-34 | 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 | ANDA090182 | 09/08/2011 | |

## Labeler - McKesson (177667227)

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

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Taro Pharmaceuticals Inc. | | 206263295 | MANUFACTURE(49348-326) |

Revised: 1/2013 McKesson