

CVS CHILDRENS ALLERGY RELIEF- cetirizine hydrochloride solution

CVS Pharmacy

CVS

Children's 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

| 1 teaspoonful (5 mL) or 2

| | |
|--|---|
| adults and children 6 years and over | 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

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: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

CVS
pharmacy®

NDC 59779-106-08

Compare to the
active ingredient in
Children's ZYRTEC®*

Original Prescription Strength

**INDOOR & OUTDOOR
ALLERGIES**

**24
HOUR**

NEW!

**Children's
ALLERGY
RELIEF**

**CETIRIZINE HYDROCHLORIDE ORAL
SOLUTION 1 mg/mL - ANTIHISTAMINE**

24 hour relief of:

- **Runny nose**
- **Itchy, watery eyes**
- **Sneezing**
- **Itchy throat or nose**

2 yrs & older

Dye & alcohol free

Sugar free

Dosing Cup

Included

4 FL OZ

(120 mL)

Bubble Gum Flavor

CVS
pharmacy®

Compare to the
active ingredient in
Children's ZYRTEC®*



Original Prescription Strength

**INDOOR & OUTDOOR
ALLERGIES**

Children's
**ALLERGY
RELIEF**

**CETIRIZINE HYDROCHLORIDE ORAL
SOLUTION 1 mg/mL - ANTIHISTAMINE**

CVS
pharmacy®

NDC 59779-106-08

Compare to the
active ingredient in
Children's ZYRTEC®*

Original Prescription Strength

**INDOOR & OUTDOOR
ALLERGIES**



Children's
**ALLERGY
RELIEF**

**CETIRIZINE HYDROCHLORIDE ORAL
SOLUTION 1 mg/mL - ANTIHISTAMINE**

24 hour relief of:

- Runny nose
- Itchy, watery eyes
- Sneezing
- Itchy throat or nose

2 yrs & older
Dye & alcohol free
Sugar free



CVS
pharmacy®

NDC 59779-106-08

Compare to the
active ingredient in
Children's ZYRTEC®*

Original Prescription Strength

**INDOOR & OUTDOOR
ALLERGIES**



NEW!

Children's
**ALLERGY
RELIEF**

**CETIRIZINE HYDROCHLORIDE ORAL
SOLUTION 1 mg/mL - ANTIHISTAMINE**

24 hour relief of:

- Runny nose
- Itchy, watery eyes
- Sneezing
- Itchy throat or nose

2 yrs & older
Dye & alcohol free
Sugar free





Dosing Cup
Included

**4 FL OZ
(120 mL)**

Bubble Gum Flavor



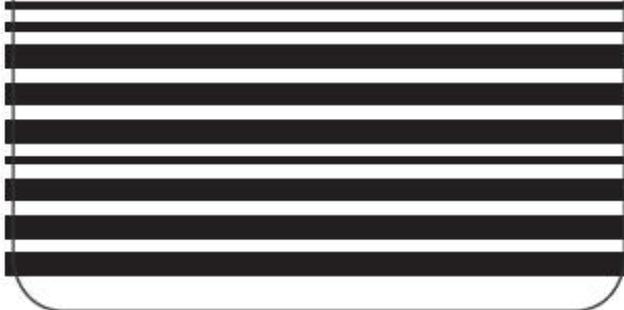
Sugar free



Dosing Cup
Included

**4 FL OZ
(120 mL)**

Bubble Gum Flavor



901417



0 50428 45563 0

039
20128-0712-0

**DO NOT USE IF CARTON IS OPENED,
OR IF PRINTED SAFETY SEAL IS BROKEN
OR MISSING**

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.

Ask a doctor before use if you have liver or kidney



Dosing Cup
Included

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

See bottom panel for expiration date.

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
© 2012 CVS/pharmacy
www.cvs.com 1-800-shop-CVS

Made in Israel
V-16793



Drug Facts

| Active ingredient (in each 5 mL teaspoonful) | Purpose |
|---|----------------|
| 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

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

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

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

Questions? Call 1-866-923-4914

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

CVS CHILDRENS ALLERGY RELIEF

cetirizine hydrochloride solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-106 |
| 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 | BUBBLE GUM (Sugar Free) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:59779-106-08 | 1 in 1 CARTON | | |
| 1 | | 120 mL in 1 BOTTLE | | |
| 2 | NDC:59779-106-01 | 1 in 1 CARTON | | |
| 2 | | 240 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 - CVS Pharmacy (062312574)

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------------|---------|-----------|------------------------|
| Taro Pharmaceutical Industries, Ltd. | | 600072078 | MANUFACTURE(59779-106) |

Revised: 11/2012

CVS Pharmacy