**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution**
**Padagis Israel Pharmaceuticals Ltd**

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**Perrigo Children's Cetirizine Hydrochloride Oral Solution 1 mg/mL 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

| | |
|---|---|
| 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 not 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**

- store between 20° to 25°C (68° to 77°F)
- do not use if carton is opened, or if printed neckband is broken or missing
- see bottom panel for lot number and expiration date

**Inactive ingredients**

artificial grape flavor, glacial acetic acid, glycerin, methylparaben, natural banana flavor, propylene glycol, propylparaben, purified water, sodium acetate, sucrose

**Questions or comments?**

**1-800-719-9260**

**Principal Display Panel**

Compare to Children's Zyrtec® active ingredient

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

2 yrs & older

Dye-Free

Grape Syrup

4 FL OZ (118 mL)

Indoor & Outdoor Allergies


# CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:45802-974 |
| **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** (UNII: 4550K0SC9B) | |
| **SUCROSE** (UNII: C151H8M554) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | YELLOW (Pale Yellow) | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | GRAPE | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:45802-974-26 | 1 in 1 CARTON | 04/15/2008 | |
| **1** | | 118 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 | ANDA090254 | 04/15/2008 | |

## Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 11/2021 Padagis Israel Pharmaceuticals Ltd