

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

-----  
**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?

## 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

Grape Syrup

Dye-Free

Indoor & Outdoor Allergies

4 FL OZ (118 mL)

Padagis™



# CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45802-974
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ACETIC ACID</b> (UNII: Q40Q9N063P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM ACETATE</b> (UNII: 4550K0SC9B)	
<b>SUCROSE</b> (UNII: C151H8M554)	

**Product Characteristics**

<b>Color</b>	YELLOW (Pale Yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

**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)