

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
Blacksmith Brands Inc.

**Pedia
Care®
2 Years & Older
Children's**

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
- 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

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	1/2 teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or 1/2 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), sucrose

Questions?

Call 1-888-474-3099

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PRINCIPAL DISPLAY PANEL - 118 mL Carton

New

**Pedia
Care®**

**2 Years & Older
Children's**

24 Hr Allergy

Cetirizine Hydrochloride

Oral Solution
1 mg/mL Antihistamine

Indoor / Outdoor

All Day Relief of:

- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Itchy Throat or Nose

Dye Free

***Grape
flavor***

4 FL OZ (118 mL)

PediaCare®
2 Years & Older
Children's

24 Hr Allergy
Cetirizine Hydrochloride

PediaCare® medicines provide effective relief for your child's cough, cold or allergy symptoms. PediaCare® Children's products come in great-tasting flavors your kids will love!

Children's Products

	Duration	Sneezing	Runny Nose	Itchy Watery Eyes	Cough
PediaCare® Allergy	4 hours	•	•	•	
PediaCare® Allergy & Cold	4 hours	•	•	•	•
PediaCare® 24 Hr Allergy	24 hours	•	•	•	

PediaCare.® We care for Kids.™

PediaCare®

2 Years & Older
Children's

24 Hr Allergy
Cetirizine Hydrochloride

New

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24 Hr Allergy
Cetirizine Hydrochloride

Oral Solution
1 mg/mL Antihistamine

Indoor Outdoor

All Day Relief of:

- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Itchy Throat or Nose

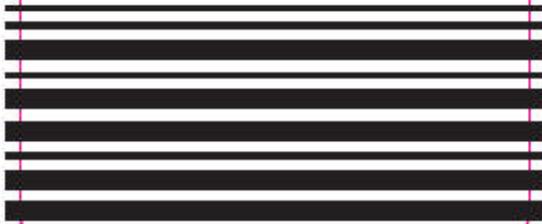
Dye Free

Grape flavor





4 FL OZ (118 mL)



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PediaCare

2 Years & Older
Children's

24 Hr Allergy

Cetirizine Hydrochloride

Indoor Outdoor

PediaCare.® We care for Kids.™



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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Directions • use only with enclosed dosing cup

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adults 65 years and older	1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) in 24 hours.
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children 2 to under 6 years of age	1/2 teaspoonful (2.5 mL) once daily. If 6 years of age or older, use 1/2 to 1 teaspoonful (2.5 to 5 mL) once daily.
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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.

Drug Facts

Active ingredient (in each 5 mL teaspoonful) Cetirizine HCl 5 mg.....	Purpose Antihistamine
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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

10 years of age	needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or 1/2 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), sucrose

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Made in Israel. PD023101

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52183-088
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: A218C7HI9T)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	

water (UNII: 059QF0K00R)

sodium acetate anhydrous (UNII: NVG71ZZ7P0)

sucrose (UNII: C151H8M554)

Product Characteristics

Color	YELLOW (Colorless to slightly yellow)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52183-088-08	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090182	04/22/2008	

Labeler - Blacksmith Brands Inc. (021411299)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Industries, Ltd.		600072078	MANUFACTURE

Revised: 12/2010

Blacksmith Brands Inc.