### LEADER CHILDRENS ALL DAY ALLERGY- cetirizine hcl solution Cardinal Health 110, LLC. dba Leader

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## Cardinal Health Children's All Day Allergy 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<br>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<br>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**

anhydrous citric acid, artificial grape flavor, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

#### Questions or comments?

1-800-719-9260

# Package/Label Principal Display Panel

Children's

All Day Allergy

Cetirizine Hydrochloride

Oral Solution 1mg/mL

Antihistamine

Indoor & Outdoor Allergies

Grape Flavor

Ages 2 Years and Older

24-Hour Relief of:

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose

Dye-Free

Sugar-Free

COMPARE TO CHILDREN'S ZYRTEC®

active ingredient

100% Money Back Guarantee

4 FL OZ (118mL)





# LEADERA

LEADER? LEADER?

# NDC 70000-02/5-1 Children's

Cetirizine Hydrochloride Oral Solution 1 mg/mL **Antihistamine** Indoor & Outdoor Allergies

# Grape

24-Hour Relief of: Sneezing Runny Nose Itchy, Watery Eyes Itchy Throat or Nose

COMPARE TO CHILDREN'S ZYRTEC® active ingredient

4 FL OZ (118mL)



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

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All LEADER™ Brand Products Have A 100% Money Back Guarantee Return to place of purchase if not satisfied.

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Ask a doctor or pharmacist before use if you are taking tranquilizers or sedativ

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- If pregnant or breast-feeding: ■ if breast-feeding; not recommended
- if pregnant: ask a health professional before use.

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#### Drug Facts (continued)

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#### Inactive ingredients

anhydrous citric acid, artificial grape flavor, propylene glycol, purified water, sodium benzoate, sorbitol

#### Questions or comments?

\*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Zyrtec®.



LOT NO.

EXP.

: 47526 E9 C3

#### LEADER CHILDRENS ALL DAY ALLERGY

cetirizine hcl solution

#### **Product Information**

**Product Type** HUMAN OTC DRUG **Route of Administration ORAL** 

**Item Code (Source)** 

NDC:70000-0215

| Active Ingredient/Active Moiety  |                              |                 |  |
|--|------------------------------|-----------------|--|
| Ingredient Name  | <b>Basis of Strength</b>     | Strength        |  |
| CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24) | CETIRIZ INE<br>HYDROCHLORIDE | 5 mg<br>in 5 mL |  |

| Inactive Ingredients                     |          |  |  |
|--|----------|--|--|
| Ingredient Name                          | Strength |  |  |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) |          |  |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)      |          |  |  |
| WATER (UNII: 059QF0KO0R)                 |          |  |  |
| SODIUM BENZOATE (UNII: OJ245FE5EU)       |          |  |  |
| SORBITOL (UNII: 506T60A25R)              |          |  |  |
| SUCRALOSE (UNII: 96K6UQ3ZD4)             |          |  |  |

| Product Characteristics |       |              |
|-------------------------|-------|--------------|
| Color                   |       | Score        |
| Shape                   |       | Size         |
| Flavor                  | GRAPE | Imprint Code |
| Contains                |       |              |

| P | Packaging            |   |                         |                       |  |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code            | Package Description                                   | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:70000-<br>0215-1 | 1 in 1 CARTON   | 02/10/2017              |                       |  |
| 1 |                      | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |  |

| Marketing Information |   |                         |                       |  |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| ANDA                  | ANDA204226                                  | 02/10/2017              |                       |  |
|                       |   |                         |                       |  |

# Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 6/2021 Cardinal Health 110, LLC. dba Leader