

**CHILDRENS CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet,  
orally disintegrating  
CVS Pharmacy, Inc.**

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***Drug Facts***

***Active ingredient (in each tablet)***

Cetirizine hydrochloride USP 10 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

Tablet melts in mouth. Can be taken with or without water.

adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 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). Avoid high humidity.
- **do not use if carton or blister unit is opened or broken**

## Inactive ingredients

betadex, citric acid anhydrous, colloidal silicon dioxide, crospovidone, dl-alpha-tocopherol, hydroxypropyl cellulose, magnesium stearate, maize maltodextrin, mannitol, microcrystalline cellulose, natural flavourings, sodium bicarbonate, sodium starch glycolate and sucralose.

## Questions or comments?

call **1-855-274-4122** (Monday - Friday 8:30 AM to 5:00 PM EST)

## Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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Made in India

Code: AP/DRUGS/04/2016

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (24 Orally Disintegrating Tablets) Blister Carton**

**CVS Health®**

Compare to the active ingredient  
in Children's Zyrtec® Allergy\*

**Indoor & outdoor Allergies**

**NDC 69842-961-76**

**Original Prescription Strength**

**Children's Allergy**

**CETIRIZINE HYDROCHLORIDE ORALLY  
DISINTEGRATING TABLETS, USP 10 mg**

**Antihistamine | Dissolve Tabs | 6 yrs. & older**

**24 HOUR**

**24 hour relief of:**

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

**Melts In Your Mouth**

**Orange Flavor**

**Actual**

**Size**

**24 TABLETS**

**Drug Facts** (continued)

**Active ingredient (in each tablet)** Cetirizine hydrochloride USP 10 mg. Antihistamine

**Purpose** Antihistamine

**Uses** Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, runny nose, 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: avoid alcoholic drinks, drowsiness may occur. 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.

**Drug Facts**

**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** Tablet melts in mouth. Can be taken with or without water. adults and children 6 years and over: one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.

ask a doctor  
adults 65 years and over  
ask a doctor  
children under 6 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). Avoid high humidity. do not use if carton or blister unit is opened or broken.

**Inactive ingredients**  
bicalcane, citric acid, amylose, colloidal silicon dioxide, croscollon, d-phenylacetamide, hydroxypropyl cellulose, magnesium stearate, maize malto-dextrin, mannitol, microcrystalline cellulose, natural flavorings, sodium bicarbonate, sodium starch glycolate and sucrose.

CVSHealth. Indoor & Outdoor Allergies

Original Prescription Strength

# Children's Allergy

CETIRIZINE HYDROCHLORIDE ORALLY  
DISINTEGRATING TABLETS, USP 10 mg  
Antihistamine | Dissolve Tabs | 6 yrs. & older



CVSHealth. Compare to the active ingredient in Children's Zyrtec® Allergy\* Indoor & Outdoor Allergies

NDC 69842-961-76

# Children's Allergy

CETIRIZINE HYDROCHLORIDE ORALLY  
DISINTEGRATING TABLETS, USP 10 mg  
Antihistamine | Dissolve Tabs | 6 yrs. & older

24 hour relief of:

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



Melts In Your Mouth  
Orange Flavor



10 Actual Size



24 TABLETS

#5668953

CVS Quality Money Back Guarantee

Code: AP/DRUGS/04/2016  
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Questions or comments? call 1-855-274-1222 (Monday - Friday 8:30 AM to 5:00 PM EST)

**Drug Facts** (continued)

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc. McNeil Consumer Healthcare Division, owner of the registered trademark Children's Zyrtec® Allergy.

Lot: P1042648 LM-4464  
Exp: P1042648

CVSHealth.

Original Prescription Strength

# Children's Allergy

CETIRIZINE HYDROCHLORIDE ORALLY  
DISINTEGRATING TABLETS, USP 10 mg  
Antihistamine | Dissolve Tabs | 6 yrs. & older

# CHILDRENS CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, orally disintegrating

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-961
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>BETADEX</b> (UNII: JV039JZZ3A)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSPVIDONE (35 .MU.M)</b> (UNII: 40UAA97IT9)	
<b>.ALPHA.-TOCOPHEROL, DL-</b> (UNII: 7QWA1RIO01)	
<b>HYDROXYPROPYL CELLULOSE (110000 WAMW)</b> (UNII: 5Y0974F5PW)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>MICROCRYSTALLINE CELLULOSE 101</b> (UNII: 7T9FYH5QMK)	
<b>MICROCRYSTALLINE CELLULOSE 102</b> (UNII: PNR0YF693Y)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	CE;10
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69842-961-76	4 in 1 CARTON	02/01/2021	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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ANDA	ANDA213557	02/01/2021	
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**Labeler** - CVS Pharmacy, Inc. (062312574)

**Registrant** - Aurohealth LLC (078728447)

**Establishment**

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(69842-961) , MANUFACTURE(69842-961)

Revised: 5/2021

CVS Pharmacy, Inc.