

**CETIRIZINE HYDROCHLORIDE (ALLERGY) - cetirizine hydrochloride tablet**  
**Aurohealth LLC**

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**Cetirizine Hydrochloride Tablets (Allergy)**

***Drug Facts***

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

**For 5 mg:**

Cetirizine hydrochloride USP 5 mg

**For 10 mg:**

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**

**For 5 mg:**

adults and children 6 years and over	1 tablet (5 mg) or 2 tablets (10 mg) once daily depending upon severity of symptoms; do not take more than 2 tablets (10 mg) in 24 hours.
adults 65 years and over	1 tablet (5 mg) once daily; do not take more than 1 tablet (5 mg) in 24 hours.
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

**For 10 mg:**

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)
- **TAMPER EVIDENT: DO NOT USE IF SEAL OVER BOTTLE OPENING IS BROKEN OR MISSING.**

**Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

### **Questions?**

call **1-855-274-4122**

Distributed by:

**AUROHEALTH LLC**

279 Princeton-Hightstown,  
East Windsor, NJ 08520

Made in India

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 5 mg (30's Tablet Container  
Carton Label)**

**AUROHEALTH**

**NDC 58602-444-09**

**\*Compare to the active  
ingredient of Zyrtec®**

**Original Prescription Strength**

**Allergy Relief  
Cetirizine Hydrochloride  
Tablets USP 5 mg**

**Antihistamine**

**Indoor & Outdoor Allergies  
5 mg Strength Tablets**

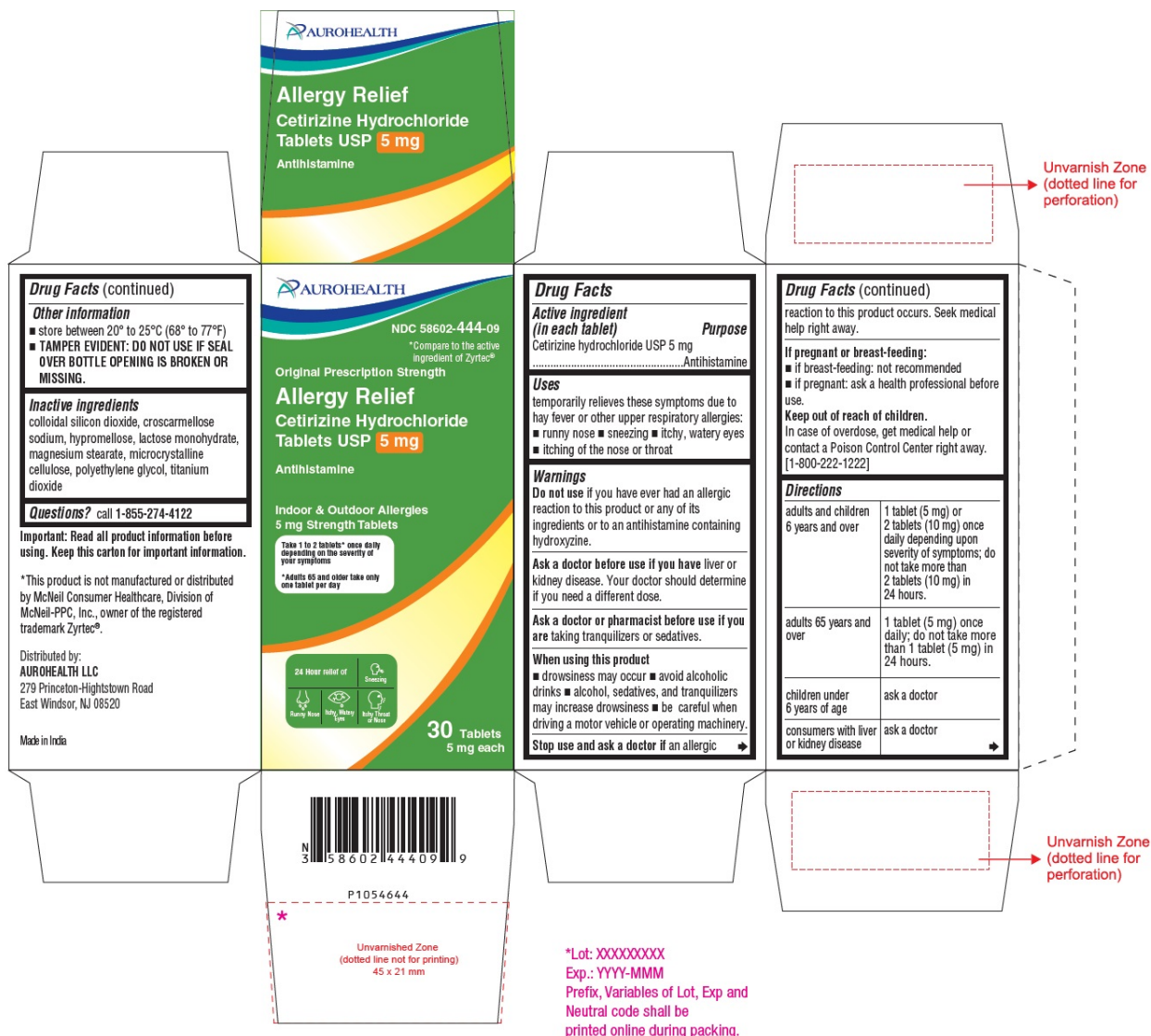
**Take 1 to 2 tablets\* once daily  
depending on the severity of  
your symptoms**

**\*Adults 65 and older take only  
one tablet per day**

24 Hour relief of

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

**30 Tablets  
5 mg each**



**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -5 mg (10 x 10 Blister Carton Label)**

**AUROHEALTH**

**NDC 58602-444-21**

**\*Compare to the active ingredient of Zyrtec®**

**Allergy Relief  
 Cetirizine Hydrochloride Tablets USP 5 mg  
 Antihistamine  
 Original Prescription Strength**

**Indoor & Outdoor Allergies  
 5 mg Strength Tablets**

**Take 1 to 2 tablets\* once daily depending on the severity of your symptoms**

**\*Adults 65 and older take only one tablet per day**

24 Hour relief of

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

**100 (10 x 10)  
unit-dose Tablets  
5 mg each**



**\*Compare to the active ingredient of Zyrtec®**

**Allergy Relief  
Cetirizine Hydrochloride Tablets USP 10 mg  
Antihistamine  
Original Prescription Strength**

**Indoor & Outdoor Allergies  
10 mg Strength Tablets**

24 Hour relief of

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

**30 Tablets  
10 mg each**



**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (10 x 10 Blister Carton Label)**

**AUROHEALTH**

**NDC 58602-445-21**

**\*Compare to the active ingredient of Zyrtec®**

**Allergy Relief  
Cetirizine Hydrochloride Tablets USP 10 mg  
Antihistamine  
Original Prescription Strength**

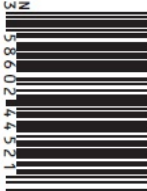
**Indoor & Outdoor Allergies  
10 mg Strength Tablets**

24 Hour relief of

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

**100 (10x10) Tablets**  
**10 mg each**

N  
31586024442718




**Allergy Relief**  
 Cetirizine Hydrochloride Tablets USP 10 mg  
 Antihistamine

**AUROHEALTH**


NDC 58602-445-21  
 \*Compare to the active ingredient of Zyrtec®

**Allergy Relief**  
 Cetirizine Hydrochloride Tablets USP 10 mg  
 Antihistamine  
 Original Prescription Strength  
 Indoor & Outdoor Allergies  
 10 mg Strength Tablets


24 Hour relief of




Runny Nose



Itchy, Watery Eyes



Itchy Throat of Nose



**100 (10x10) Tablets**  
**10 mg each**

P1054579  
 Unvarnished Zone  
 (dotted area printing)  
 80 x 26 mm

\*Lot: XXXXXXXX  
 Exp.: YYYY-MMM  
 Prefix, Variables of Lot, Exp and Neutral code shall be printed online during packing.

**Allergy Relief**  
 Cetirizine Hydrochloride Tablets USP 10 mg  
 Antihistamine

Keep the carton. It contains important information.  
 This package is child resistant.

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., owner of the registered trademark Zyrtec®.

Distributed by:  
**AUROHEALTH LLC**  
 279 Princeton-Hightstown Road  
 East Windsor, NJ 08520  
 Made in India

**Drug Facts (cont. n.d.)**

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

**Uses** Temorarily relieves these symptoms due to hay fever or other upper respiratory allergies: runny nose, sneezing, itchy, watery eyes, itching of the throat or itchy nose.

**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 by other name.

**Ask a doctor before use if you are** pregnant or breastfeeding, or if you are taking other prescription or over-the-counter drugs. Your doctor should determine if you need a different dose.

**Ask a doctor before use if you are** liver or kidney compromised, ask a doctor if you are taking other prescription or over-the-counter drugs.

**Other information** Store at controlled room temperature (20° to 25° C (68° to 77° F)).

**Inactive ingredients** Cellulose, croscarmellose sodium, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide.

**Questions?** call 1-855-274-4122

**Directions** Adults and children 6 years and over: do not take more than one 10 mg tablet once daily. Children 6 years and over: 5 mg product in 24 hours. A 10 mg product is less severe than 5 mg product.

**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 by other name.

**Ask a doctor before use if you are** pregnant or breastfeeding, or if you are taking other prescription or over-the-counter drugs. Your doctor should determine if you need a different dose.

**Ask a doctor before use if you are** liver or kidney compromised, ask a doctor if you are taking other prescription or over-the-counter drugs.

**Other information** Store at controlled room temperature (20° to 25° C (68° to 77° F)).

**Inactive ingredients** Cellulose, croscarmellose sodium, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide.

**Questions?** call 1-855-274-4122

**LEBG9420**



# CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-444
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	WHITE (White to Off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	X;35
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-444-09	1 in 1 CARTON	08/05/2015	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-444-17	1 in 1 CARTON	08/05/2015	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-444-47	75 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	08/05/2015	
4	NDC:58602-444-41	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	
5	NDC:58602-444-21	10 in 1 CARTON	08/05/2015	
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090760	08/05/2015	

## CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-445
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (White to Off-white)	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	X;36
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-445-09	1 in 1 CARTON	08/05/2015	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-445-17	1 in 1 CARTON	08/05/2015	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-445-47	75 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	08/05/2015	
4	NDC:58602-445-15	1 in 1 CARTON	08/05/2015	
4		60 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-445-19	1 in 1 CARTON	08/05/2015	

5		90 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-445-94	1 in 1 CARTON	08/05/2015	
6		100 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:58602-445-38	1 in 1 CARTON	08/05/2015	
7		300 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:58602-445-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	
9	NDC:58602-445-41	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	
10	NDC:58602-445-21	10 in 1 CARTON	08/05/2015	
10		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
11	NDC:58602-445-01	1 in 1 CARTON	08/05/2015	
11		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
12	NDC:58602-445-60	1 in 1 CARTON	08/05/2015	
12		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
13	NDC:58602-445-54	1 in 1 CARTON	08/05/2015	
13		70 in 1 BOTTLE; Type 0: Not a Combination Product		
14	NDC:58602-445-65	2 in 1 CARTON	11/21/2019	
14		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090760	08/05/2015	

## CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-812
<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	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSE 2910 (5 MPA.S)</b> (UNII: R75537T0T4)	

<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE (White to Off-white)	<b>Score</b>	2 pieces
<b>Shape</b>	RECTANGLE (off-rectangular)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	X;2;0
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-812-09	1 in 1 CARTON	08/05/2015	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-812-17	1 in 1 CARTON	08/05/2015	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-812-99	75 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	08/05/2015	
4	NDC:58602-812-23	1 in 1 CARTON	08/05/2015	
4		120 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-812-39	1 in 1 CARTON	08/05/2015	
5		365 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-812-41	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	
7	NDC:58602-812-04	10 in 1 CARTON	08/05/2015	
7	NDC:58602-812-83	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090760	08/05/2015	

**Labeler** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(58602-444, 58602-445, 58602-812) , MANUFACTURE(58602-444, 58602-445, 58602-812)