

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, film coated**  
**Mylan Institutional Inc.**

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**Drug Facts**

**CETIRIZINE HCl**  
**10 mg TABLETS, USP**

**Antihistamine**

**Indoor & Outdoor Allergies**

**TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**

**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.

**Directions (24 Hour Relief)**

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 at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]**

**Inactive ingredients**

Anhydrous lactose, colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, sodium lauryl sulfate, titanium dioxide, and triacetin

**Questions? 1-800-848-0462**

- Serious side effects associated with use of this product may be reported to this number.

**HOW SUPPLIED**

Cetirizine Hydrochloride Tablets, USP are available as follows:

10 mg - White, film-coated, round, biconvex, beveled edge, unscored tablets debossed with **M** on one side of the tablet and **C37** on the other side.

NDC 51079-597-20 - Unit dose blister packages of 100 (10 cards of 10 tablets each).

**Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]**

Manufactured for:

**Mylan Pharmaceuticals Inc.**  
Morgantown, WV 26505 U.S.A.

Made in India

Code No.: MH/DRUGS/25/NKD/89

Distributed by:

**Mylan Institutional Inc.**  
Rockford, IL 61103 U.S.A.

S-12769  
10/21

**PRINCIPAL DISPLAY PANEL - 10 mg**

**NDC 51079-597-20**

**Cetirizine HCl**  
**Tablets, USP**  
**10 mg**

**Antihistamine**

**Indoor & Outdoor Allergies**

**24 Hour Relief**

(See Uses section of enclosed leaflet)

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Manufactured for:

**Mylan Pharmaceuticals Inc.**  
Morgantown, WV 26505 U.S.A.

Made in India

S-12721

- This unit dose package is not child resistant.
- For institutional use only.
- Keep this and all drugs out of the reach of children.
- This container provides light-resistance.
- See window for lot number and expiration date.

Distributed by:

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Rockford, IL 61103 U.S.A.

NDC 51079-597-20

**Cetirizine HCl**  
**Tablets, USP** **10 mg**

Antihistamine

Indoor & Outdoor Allergies

24 Hour Relief

(See Uses section of enclosed leaflet)

C37

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NDC 51079-597-20

**Cetirizine HCl**  
**Tablets, USP** **10 mg**

Antihistamine

C37



100 Tablets (10 x 10)

**Drug Facts**

Active Ingredient (In each tablet)	Purpose
Cetirizine hydrochloride USP, 10 mg . . . . .	Antihistamine

**Uses:** See enclosed leaflet

**Warnings:** See enclosed leaflet

**Directions:** See enclosed leaflet

**Other information** ■ Store at 20° to 25°C (68° to 77°F).  
[See USP Controlled Room Temperature.]

Code No.: MH/DRLGS/25/NKD/89

**Inactive Ingredients:** Anhydrous lactose, colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, sodium lauryl sulfate, titanium dioxide, and triacetin.

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**Mylan**<sup>®</sup>

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Rockford, IL 61103 U.S.A.



GTIN XXXXXXXXXXXXXXXXXXXX  
S/N XXXXXXXXXXXXXXX  
EXP MM YYYY  
LOT XXXXXXXX

## **CETIRIZINE HYDROCHLORIDE**

cetirizine hydrochloride tablet, film coated

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51079-597(NDC:0378-3637)
<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>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	M;C37
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51079-597-20	100 in 1 BOX, UNIT-DOSE	03/30/2012	
1	NDC:51079-597-01	1 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	ANDA076677	03/30/2012	

**Labeler** - Mylan Institutional Inc. (039615992)

