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

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)

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

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:
Mylan Institutional Inc.
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

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

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

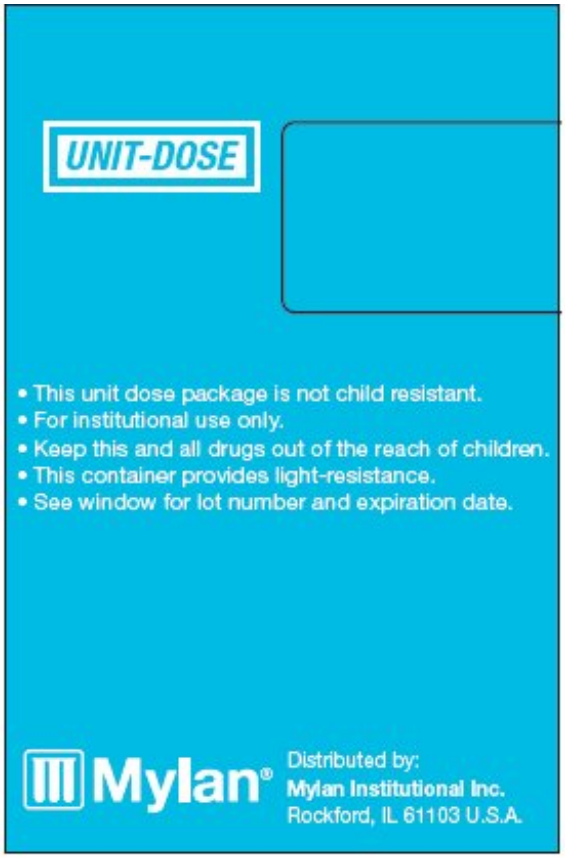
Other Information ■ **Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]**

Code No.: MH/DRUGS/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.

Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.
Made in India

S-12721



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51079-597(NDC:0378-3637)
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	M;C37
Contains			

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)