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)

<table>
<thead>
<tr>
<th>Adults and children 6 years and over</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults 65 years and over</td>
<td>ask a doctor</td>
</tr>
<tr>
<td>Children under 6 years of age</td>
<td>ask a doctor</td>
</tr>
<tr>
<td>Consumers with liver or kidney disease</td>
<td>ask a doctor</td>
</tr>
</tbody>
</table>

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 by:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.
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 by:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.
S-9828 R6

• 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.
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.

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.]

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®
Distributed by:
Mylan Institutional Inc.
Rockford, IL 61103 U.S.A.
# CETIRIZINE HYDROCHLORIDE
cetirizine hydrochloride tablet, film coated

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:51079-597(NDC:0378-3637)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)</td>
<td>CETIRIZINE HYDROCHLORIDE</td>
<td>10 mg</td>
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</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)</td>
<td></td>
</tr>
<tr>
<td>SILICON DIOXIDE (UNII: ETJ7Z6XBU4)</td>
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<tr>
<td>HYPMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)</td>
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<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6I30)</td>
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<tr>
<td>MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)</td>
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<tr>
<td>POLYDEXTROSE (UNII: VH2XOU12IE)</td>
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<tr>
<td>POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)</td>
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<tr>
<td>SODIUM LAURYL SULFATE (UNII: 368GB5141J)</td>
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</tr>
<tr>
<td>TITANIUM DIOXIDE (UNII: 15FIX9V2JP)</td>
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<tr>
<td>TRIACETIN (UNII: XHX3C3X673)</td>
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</table>

## Product Characteristics

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

## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:51079-597-20</td>
<td>100 in 1 BOX, UNIT-DOSE</td>
<td>03/30/2012</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>NDC:51079-597-01</td>
<td>1 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>ANDA</td>
<td>ANDA076677</td>
<td>03/30/2012</td>
<td></td>
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</tbody>
</table>

## Labeler

- Mylan Institutional Inc. (039615992)