

**CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet, film coated**  
**Physicians Total Care, Inc.**

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**Drug Facts**

**Active ingredient**

Cetirizine Hydrochloride 5 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

adults and children 6 years and over	1 to 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.
adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in 24 hours
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)

## Inactive ingredients

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

## Questions?

call 1-877-446-3679

**Mylan Pharmaceuticals Inc.**  
**Morgantown, WV 26505**

**PRINCIPAL DISPLAY PANEL - 5 mg Hives Relief**

**NDC 54868-5855-0**

Cetirizine Hydrochloride  
Tablets 5 mg  
antihistamine

**24**  
**HOUR**

**Relief of**  
**ITCHING**  
**Due to Hives**

**Tamper Evident: do not use if foil seal under cap**  
**is missing, open or broken**



# CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, film coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-5855(NDC:0378-3635)
Route of Administration	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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

## Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	M;C35
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-5855-0	100 in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076677	01/29/2008	

**Labeler** - Physicians Total Care, Inc. (194123980)

**Establishment**

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 5/2012

Physicians Total Care, Inc.