

**CETIRIZINE- cetirizine hydrochloride tablet, film coated  
REMEDYREPACK INC.**

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**Major Pharmaceuticals Cetirizine Drug Facts**

**Active ingredient (in each tablet)**

Cetirizine HCl 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

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 20-25 °C (68-77 °F)
- do not use if printed foil under cap is broken or missing

## Inactive ingredients

corn starch, FD&C blue no. 1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin

## Questions or comments?

1-800-719-9260

DRUG: Cetirizine

GENERIC: Cetirizine Hydrochloride

DOSAGE: TABLET, FILM COATED

ADMINISTRATION: ORAL

NDC: 70518-1705-0

NDC: 70518-1705-1

NDC: 70518-1705-2

COLOR: white

SHAPE: OVAL

SCORE: No score

SIZE: 10 mm

IMPRINT: 4H2

PACKAGING: 30 in 1 BLISTER PACK

PACKAGING: 28 in 1 BLISTER PACK

PACKAGING: 30 in 1 BOTTLE PLASTIC

ACTIVE INGREDIENT(S):

- CETIRIZINE HYDROCHLORIDE 10mg in 1

INACTIVE INGREDIENT(S):

- MAGNESIUM STEARATE
- POLYETHYLENE GLYCOLS
- POLYDEXTROSE
- POVIDONES

- TITANIUM DIOXIDE
- FD&C BLUE NO. 1
- HYPROMELLOSES
- STARCH, CORN
- LACTOSE MONOHYDRATE
- TRIACETIN

## Cetirizine HCl

**10 mg Tablet**

ID #: 4H2

NDC #: 70518-1705-00

LOT #:

MFG: Major Pharma, Livonia, MI 48150

**NOT FOR RETAIL SALE**

QTY: **30**

**Expires:**

Shape: Oval

Ref #: 00904-6717-40

**Directions For Use: See Package Insert**

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by:

RemedyRepack Inc., Indiana, PA 15701, 1-724-465-8762



# Cetirizine HCl

**10 mg Tablet**

QTY: **28**

ID #: 4H2

NDC #: 70518-1705-01

LOT #:

MFG: Major Pharma, Livonia, MI 48150

**NOT FOR RETAIL SALE**

**Expires:**

Shape: Oval

Ref #: 00904-6717-40

**Directions For Use: See Package Insert**

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by:

RemedyRepack Inc., Indiana, PA 15701, 1-724-465-8762



# Cetirizine HCl

**10 mg Tablet**

QTY: **30**

ID #: 4H2

NDC #: 70518-1705-02

LOT #:

MFG: Major Pharma, Livonia, MI 48150

**NOT FOR RETAIL SALE**

**Expires:**

Shape: Oval

Ref #: 00904-6717-40

**Directions For Use: See Package Insert**

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by:

RemedyRepack Inc., Indiana, PA 15701, 1-724-465-8762



# CETIRIZINE

cetirizine hydrochloride tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70518-1705(NDC:0904-6717)
<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	10 mg

## Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	4H2
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70518-1705-0	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/03/2018	
2	NDC:70518-1705-1	28 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/30/2019	
3	NDC:70518-1705-2	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/16/2019	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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ANDA	ANDA078336	12/03/2018	
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**Labeler** - REMEDYREPACK INC. (829572556)

Revised: 9/2019

REMEDYREPACK INC.