

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablets tablet, film coated**  
**Preferred Pharmaceuticals Inc.**

-----  
**Cetirizine Hydrochloride Tablets**

***Drug Facts***

**Active ingredient (in each tablet)**

Cetirizine HCl, 10mg

**Purpose**

Antihistamine

**Uses**

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

1. runny nose
2. sneezing
3. itchy, watery eyes
4. itching of the nose or throat

**Warnings**

**Ask a doctor before use if you have**

**Do not use if** you have ever had an allergic reaction to this product or any of its ingredients or to an antihistaminecontaining 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**

**Ask a doctor or pharmacist before use if you are** taking tranquilizers or sedatives.

**When using this product**

1. drowsiness may occur
2. avoid alcoholic drinks
3. alcohol, sedatives, and tranquilizers may increase drowsiness

4. be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if**

**Stop use and ask a doctor if**

an allergic reaction to this product occurs. Seek medical help right away.

**If pregnant or breast-feeding:**

1. If breast-feeding: not recommended
2. if pregnant: ask a health professional before use.

**Keep out of reach of children**

**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   | 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**

1. store between 20° to 25°C (68° to 77°F)  
**Repackaged By: Preferred Pharmaceuticals Inc.**

**Inactive ingredients**

hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, starch, titanium dioxide.

**Questions?**

call **1-888-375-3784.**

NDC 68788-8435

**Bottle Label**

# Cetirizine Hydrochloride

## Tablet 10mg

Generic for Zyrtec

Each tablet contains Cetirizine HCl 10mg

**Pkg Size:** Exp Date:

Lot#:

Batch#:

Ins:

Mfg: Dr. Reddys Laboratories Inc

Prod#:

Warning

Do not use if you ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine. Ask doctor before use if you have liver or kidney disease, or if you are taking tranquilizers or sedatives. When using this product drowsiness may occur, avoid alcoholic drinks. Store between 20° to 25°C (68° to 77°F). Keep this and all medication out of the reach of children. Tablet is oval, white, and imprinted with C



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed

Cetirizine Hydrochloride Tablet 10 mg

Qty: Ins:  
Lot#: Bat#:

Prod# (NDC):

Cetirizine Hydrochloride Tablet 10 mg

Qty: Ins:  
Lot#: Bat#:  
Prod# (NDC):

Cetirizine Hydrochloride Tablet 10 mg

Qty: Ins:  
Insurance NDC:  
Lot#: Bat#:

Cetirizine Hydrochloride Tablet 10 mg

Qty: Ins:  
Lot#: Bat#:  
Prod# (NDC):



Directions English

Take \_\_\_ tablet(s) every \_\_\_ hours. Use as directed by your doctor



Instrucciones Espanol:

Tomar \_\_\_ tableta(s) cada \_\_\_ horas. Usar según lo dirigido por su doctor

Log  
Chart  
Billing  
Patient

## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablets tablet, film coated

### Product Information

|                                |                |                           |                               |
|--------------------------------|----------------|---------------------------|-------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68788-8435(NDC:43598-811) |
| <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>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO) |          |
| <b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)       |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)        |          |
| <b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)   |          |
| <b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)     |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)              |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)          |          |

### Product Characteristics

|                 |       |                     |          |
|-----------------|-------|---------------------|----------|
| <b>Color</b>    | WHITE | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL  | <b>Size</b>         | 7mm      |
| <b>Flavor</b>   |       | <b>Imprint Code</b> | C        |
| <b>Contains</b> |       |                     |          |

### Packaging

Marketing Start      Marketing End

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68788-8435-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 04/27/2023           |                    |
| 2 | NDC:68788-8435-6 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 04/27/2023           |                    |
| 3 | NDC:68788-8435-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 04/27/2023           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA078343                               | 04/27/2023           |                    |

**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals Inc. (791119022)

### Establishment

| Name                           | Address | ID/FEI    | Business Operations |
|--------------------------------|---------|-----------|---------------------|
| Preferred Pharmaceuticals Inc. |         | 791119022 | REPACK(68788-8435)  |

Revised: 3/2024

Preferred Pharmaceuticals Inc.