CETIRIZINE- cetirizine hydrochloride tablet, film coated Cardinal Health 107, LLC

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 | one 10 mg tablet once daily; do not take more than one 10 |
|---------------------------|---|
| years and over | 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 | ask a doctor |
| age | |
| consumers with liver or | ask a doctor |
| kidney disease | |

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

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, distributor of Zytec@.

Retain carton for complete Drug Facts.

Gluten Free

Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

www.major-rugby.com

Packaged and Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268 USA

Refer to package label for Distributor's NDC Number

Overbagged with 10 film-coated tablets per bag, NDC 55154-0194-0

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only. Keep this and all drugs out of the reach of children.

Distributed By:

Cardinal Health

Dublin, OH 43017

L6083703-11025 / L6083703-21025

| Rev. 10/24 | M-05 | Re-Order No. 700885 |
|------------|------|---------------------|
| Rev. 03/25 | M-05 | Re-order No. 303077 |

Principal Display Panel

NDC 55154-0194-0

Original Prescription Strength

Cetirizine Hydrochloride Tablets, 10 mg

Antihistamine

10 TABLETS



Original Prescription Strength Cetirizine Hydrochloride Tablets, 10 mg **Antihistamine**

10 TABLETS

Active ingredient (in each tablet) Cetirizine HCI 10 mg

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

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

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

consumers with liver or

ask a doctor

kidney disease

STORAGE: store between 20 - 25°C (68 - 77°F)

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only. Keep this and all drugs out of the reach of children.

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.

Questions or comments? 1-800-719-9260

The drug product contained in this package is from NDC # 0904-6717, Major® Pharmaceuticals

Distributed by: MAJOR® PHARMACEUTICALS Indianapolis, IN 46268 USA www.major-rugby.com

Exp:

Distributed by Cardinal Health Dublin, OH 43017

L6083703-11025

Lot:

Distributed by Cardinal Health Dublin, OH 43017

L6083703-21025

WARNING CONT: When using this product a drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness **g** be careful when driving a motor vehicle or operating machinery Stop and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding: a 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)

CETIRIZINE

cetirizine hydrochloride tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55154-0194(NDC:0904-7510) **Route of Administration ORAL**

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|------------------------------|----------|
| CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24) | CETIRIZ INE HYDROCHLORIDE | 10 mg |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| STARCH, CORN (UNII: O8232NY3SJ) | | |
| FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM) | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | |

| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
|---|--|
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| POLYDEXTROSE (UNII: VH2XOU12IE) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |

| Product Characteristics | | | | |
|-------------------------|-------|--------------|----------|--|
| Color | WHITE | Score | no score | |
| Shape | OVAL | Size | 10mm | |
| Flavor | | Imprint Code | 4H2 | |
| Contains | | | | |

| Packaging | | | | | |
|-----------|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:55154- 0194-0 | 10 in 1 BAG | 11/07/2025 | | |
| 1 | | 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 | ANDA078336 | 11/07/2025 | |
| | | | |

Labeler - Cardinal Health 107, LLC (118546603)

Revised: 11/2025 Cardinal Health 107, LLC