

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 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
- Overbagged with 10 tablets per bag, NDC 55154-8081-0

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

Distributed By:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Dr., Suite 233

Livonia, MI 48152

**Distributed by:
Cardinal Health**

Dublin, OH 43017

L5534953-10124

L5534953-20124

Principal Display Panel

Cetirizine Hydrochloride Tablets

10 mg

10 Tablets



J109

NDC 55154-8081-0

CETIRIZINE HYDROCHLORIDE
TABLETS 10 mg
Original Prescription Strength
Antihistamine

10 TABLETS

Drug Facts

Active Ingredient (in each tablet)
Cetirizine HCl 10 mg

Purpose
Antihistamine

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

Other information ■ store between 20- 25°C (68- 77°F)

Warnings

If pregnant or breast-feeding: ■ if breast-feeding: not recommended

■ if pregnant: ask a health professional before use.

WARNING:This Unit Dose package is not child resistant and is Intended for Institutional Use Only. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Keep this and all drugs out of reach of children.

Questions or comments? 1-800-616-2471

Distributed by MAJOR® PHARMACEUTICALS
Indianapolis, IN 46268

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Dublin, OH 43017

L5534953-10124

Lot: Exp:

Distributed by Cardinal Health

Dublin, OH 43017

L5534953-20124

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.

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CETIRIZINE

cetirizine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-8081(NDC:0904-6717)
Route of Administration	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: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (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

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:55154-8081-0	10 in 1 BAG	06/29/2018	
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	06/29/2018	

Labeler - Cardinal Health 107, LLC (118546603)