

SHOPRITE ALLERGY- cetirizine hydrochloride tablet
Wakefern Food Corporation

ShopRite Allergy 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

- do not use if blister unit is broken or torn
- store between 20° to 25°C (68° to 77°F)

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-SHOPRITE

Principal Display Panel

Compare to: Active Ingredient in Zyrtec®

ORIGINAL PRESCRIPTION STRENGTH

ALLERGY

Cetirizine Hydrochloride Tablets, 10 mg – Antihistamine

INDOOR & OUTDOOR ALLERGIES

24 Hour Relief of: Sneezing; Runny Nose; Itchy, Watery Eyes; Itchy Throat or Nose

actual size

14 tablets



ORIGINAL PRESCRIPTION STRENGTH

ALLERGY

Cetirizine Hydrochloride Tablets, 10 mg • Antihistamine

Compare to: Active Ingredient in Zyrtec®*



ORIGINAL PRESCRIPTION STRENGTH

ALLERGY

Cetirizine Hydrochloride Tablets, 10 mg • Antihistamine

INDOOR & OUTDOOR ALLERGIES

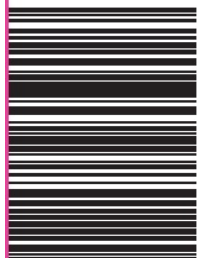
24 Hour

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Drug Facts (continued)

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Your complete satisfaction or your money back. We welcome your questions and comments. Call: 1-800-ShopRite or Email: www.shoprite.com

TEAR ALONG PERFORATION. PEEL OFF PAPER AND PUSH PRODUCT THROUGH FOIL. IF DIFFICULT TO OPEN USE SCISSORS.

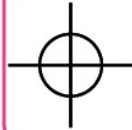


Drug Facts (continued)

Questions or comments? 1-800-SHOPRITE

*This product is not manufactured or distributed by McNeil Consumer Healthcare, division of McNeil-PPC, Inc., distributor of Zyrtec®.

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SHOPRITE ALLERGY

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-458
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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41190-458-66	1 in 1 CARTON	08/14/2013	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41190-458-72	1 in 1 CARTON	08/19/2013	
2		60 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41190-458-39	1 in 1 CARTON	06/07/2016	
3		30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078336	08/14/2013	

Labeler - Wakefern Food Corporation (069722418)