ALL DAY ALLERGY RELIEF- cetirizine hcl tablet
ASSURED (Greenbrier International, Inc.)

Cetirizine Hydrochloride Tablets

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.

Directions

Adults and children 6 years and over	Take 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 to 25°C (68 to 77°F)

Inactive Ingredients

colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, titanium dioxide.

Questions or comments?

Call toll free 1-877-753-3935 Monday-Friday 9am-5pm EST.

Principal Display Panel

† Compare to the active ingredient in Zyrtec®

All Day

Allergy Relief

Cetirizine Hydrochloride tablets, 10 mg

Antihistamine

Relief of:

- Runny nose
- sneezing
- Itchy, watery eyes
- Itchy throat or nose

Indoor & Outdoor allergies

†This product is not manufactured or distributed by McNeil Consumer Healthcare Division of McNeil-PPC, Inc., owner of the registered trademark Zyrtec®

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT

PACKAGE. USE ONLY IF BLISTERS ARE INTACT.
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
PRODUCT OF INDIA

Package Labeling


Drug Facts
Active ingredient (in each tablet)
Purpose
Cetirizine HCl 10 mg
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.
Directions
adults and children 6 years and over: Take 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° to 25°C (68° to 77°F)
Inactive ingredients colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, titanium dioxide.
Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST
ASSURED
ALL DAY
Allergy Relief
Cetirizine Hydrochloride Tablets, 10 mg • Antihistamine
Relief of: Running Nose, Sneezing, Itchy, Watery Eyes, Itchy Throat or Nose
NDC 33992-0128-4
†Compare to the active ingredient in Zyrtec®
ALL DAY
Allergy Relief
Cetirizine Hydrochloride Tablets, 10 mg • Antihistamine
Relief of: Running Nose, Sneezing, Itchy, Watery Eyes, Itchy Throat or Nose
Indoor Outdoor Allergies
14 TABLETS
THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
Lot No.:
Exp. Date:
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Distributed by:
Greenbrier International, Inc.

Cetirizine HCl 10 mg

ALL DAY ALLERGY RELIEF

cetirizine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:33992-0128
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	W989
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:33992-0128-4	1 in 1 CARTON		
1		14 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078427	10/19/2012	

Labeler - ASSURED (Greenbrier International, Inc.) (610322518)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 12/2012 ASSURED (Greenbrier International, Inc.)