

QUALITY CHOICE CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Chain Drug Marketing Association Inc.

Quality Choice® Cetirizine Hydrochloride

Drug Facts

Active ingredient (in each tablet)

Cetirizine HCl, USP 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

and over	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

- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**
- store between 20° to 25° C (68° to 77° F)

Inactive ingredients

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

Questions?

call **1-800-406-7984**

Distributed by C.D.M.A., Inc.©
43157 W. Nine Mile
Novi, MI 48376-0995

PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Carton

QUALITY®
CHOICE

NDC 63868-132-90

†Compare to
Active Ingredient in
ZYRTEC®

Original Prescription Strength

All Day Allergy

Cetirizine HCl Tablets, USP
10 mg | Antihistamine

Indoor & Outdoor Allergies

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

90 Tablets 10 mg Each



Original Prescription Strength

All Day Allergy

Cetirizine HCl Tablets, USP
10 mg | Antihistamine



NDC 63868-132-90

[†]Compare to
Active Ingredient in
ZYRTEC[®]

Original Prescription Strength

All Day Allergy

Cetirizine HCl Tablets, USP
10 mg | Antihistamine

Indoor & Outdoor Allergies

24 Hour Relief of:

Sneezing | Runny Nose

Itchy, Watery Eyes | Itchy Throat or Nose



90 Tablets 10 mg Each



Original Prescription Strength

All Day Allergy

Cetirizine HCl Tablets, USP
10 mg | Antihistamine

Keep the carton. It contains important information. See end panel for expiration date.

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Cetirizine HCl USP 10 mg.....Antihistamine</p> <p>Purpose</p> <p>temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat </p> <p>Warnings</p> <p>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.</p> <p>Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.</p> <p>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</p> <p>When using this product <ul style="list-style-type: none"> ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery </p> <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p>	
<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding: <ul style="list-style-type: none"> ■ if breast-feeding: not recommended ■ if pregnant: ask a health professional before use. </p> <p>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).</p>	
<p>Directions</p> <p>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.</p> <p>adults 65 years and over ask a doctor</p> <p>children under 6 years of age ask a doctor</p> <p>consumers with liver or kidney disease ask a doctor</p>	
<p>Other information</p> <p>■ TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.</p> <p>■ store between 20° to 25° C (68° to 77° F)</p> <p>Inactive ingredients corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide</p> <p>Questions? call 1-800-406-7984</p>	

Expiration Date:

ea

† All trademarks are prop
is not affiliated with the

R0714



6 35515 95898

Non Varnish Ar

Batch No.



5110869

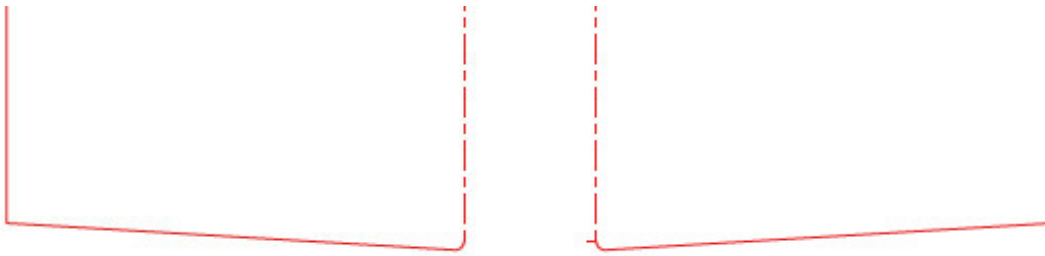
erty of their respective owners. This product
makers/owners of Zyrtec®.



Distributed by C.D.M.A., Inc.®
43157 W. Nine Mile
Novi, MI 48376-0995
www.qualitychoice.com
Questions: 248-448-9300



5110869



QUALITY CHOICE CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-132
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	RECTANGLE (rounded off)	Size	9mm
Flavor		Imprint Code	R152
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-132-14	14 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/27/2007	
2	NDC:63868-132-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2007	
3	NDC:63868-132-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077498	12/27/2007	

Labeler - Chain Drug Marketing Association Inc. (011920774)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(63868-132)

Revised: 8/2018

Chain Drug Marketing Association Inc.