

INDOOR OUTDOOR ALLERGIES- cetirizine hcl tablet
PLD Acquisitions LLC DBA Avéma Pharma Solutions

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, sedative, 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 pregnant: ask a health professional before use
- If breast-feeding: not recommended

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

corn starch, hypromellose, lactose monohydrate, macrogol, magnesium stearate, povidone, titanium dioxide.

Questions or comments?**Principal Display Panel**

*Compare to the active ingredient in Zyrtec®

Cetirizine HCL Tablets, USP 10 mg

Antihistamine

Indoor & Outdoor allergies

24 hour relief of

- sneezing
- Runny nose
- Itchy, watery eyes

- Itchy throat or nose

Tablets

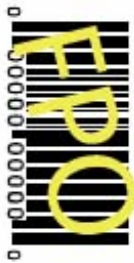
*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Zyrtec®

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Product Label

Exp. Date:
Lot No.:
PLD-A5ZZA F0000000



Distributed by:
Specific to customer's labeling guide. Must state either:
(manufacturer, packer, or distributor)

Drug Facts	Purpose
Active ingredient (in each tablet) cetirizine HCl 10 mg.....Antihistamine	
Uses 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. 	
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.	
As a doctor, because use if you have liver or kidney disease. Your doctor should determine if you need a different dose.	
As a doctor or pharmacist, because use if you are taking tranquilizers or sedatives.	
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 	
Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.	
If pregnant or breast-feeding: <ul style="list-style-type: none"> ■ If pregnant, ask a health professional before use ■ If breast-feeding, not recommended 	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	

Cetirizine HCl Tablets, USP 10 mg Antihistamine

Indoor & outdoor allergies

24-hour relief of

- ✓ Sneezing
- ✓ Itchy, watery eyes
- ✓ Runny nose
- ✓ Itchy throat or nose

300 Tablets

NDC 63548-0739-3
*Compare to the active ingredient in Zyrtec®



Actual Size

Drug Facts (continued)	
Directions	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
child or 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	corn starch, hypromellose, lactose monohydrate, macrogl, magnesium stearate, polydiox, titanium dioxide
Questions or comments?	Call 1-800-300-3000, MON-FRI 8 AM-8 PM EST

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INDOOR OUTDOOR ALLERGIES

cetirizine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63548-0739
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
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	432
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63548-0739-3	1 in 1 BOX	07/01/2019	
1		300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077946	07/01/2019	

Labeler - PLD Acquisitions LLC DBA Avéma Pharma Solutions (804087794)

Revised: 2/2023

PLD Acquisitions LLC DBA Avéma Pharma Solutions