# CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablets tablet, film coated

Dr. Reddy's Laboratories Inc.

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#### **Cetirizine Hydrochloride Tablets**

### **Drug Facts**

#### Active ingredient (in each tablet)

Cetirizine HCl, 10mg

#### **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**

•	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**

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

#### Questions?

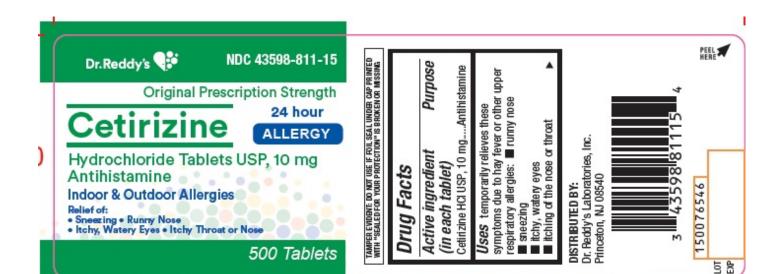
call **1-888-375-3784**.

#### Carton

10 mg carton Labeling



#### **Bottle Label**



*Drug Facts* (continued)

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Other information

kidney disease

with liver or consumers

## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablets tablet, film coated

*Drug Fact*s (continued

Directions

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-811
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
	CETIRIZ INE HYDROCHLORIDE	10 mg	

Inactive Ingredients				
Ingredient Name	Strength			
HYPROMELLOSES (UNII: 3NXW29V3WO)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POVIDONE (UNII: FZ989GH94E)				
STARCH, CORN (UNII: O8232NY3SJ)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				

Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	7mm	
Flavor		Imprint Code	С	
Contains				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:43598-811- 30	1 in 1 CARTON	12/17/2018				
1		300 in 1 BOTTLE; Type 0: Not a Combination Product					
2	NDC:43598-811- 05	1 in 1 CARTON	12/17/2018				
2		500 in 1 BOTTLE; Type 0: Not a Combination Product					
3	NDC:43598-811- 90	1 in 1 CARTON	12/17/2018				
3		90 in 1 BOTTLE; Type 0: Not a Combination Product					
4	NDC:43598-811- 12	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/03/2019				
5	NDC:43598-811- 15	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/03/2019				
6	NDC:43598-811- 13	300 in 1 BOTTLE; Type 0: Not a Combination Product	09/03/2019				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078343	12/17/2018	

## Labeler - Dr. Reddy's Laboratories Inc. (802315887)

Revised: 12/2022 Dr. Reddy's Laboratories Inc.