CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablets tablet, film coated Dr. Reddy's Laboratories Inc.

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

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Warnings

Ask a doctor before use if you have

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

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

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

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	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours.		
years and over	A 5 mg product may be appropriate for less severe symptoms.		
adults 65 years and	ask a doctor		
over	ask a doctor		
children under 6	ask a doctor		
years of age	dSK d UUCIUI		
consumers with liver	ask a doctor		
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**.

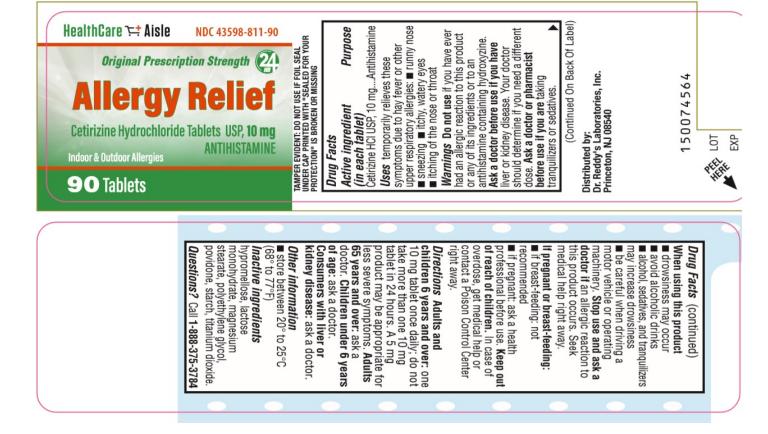
Carton

10 mg carton Labeling



Bottle Label

CETIRIZINE HYDROCHLORIDE



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

Active Ingredient/Active Moiety Ingredient Name Basis of Strength CETIRIZINE HYDRO CHLO RIDE (UNII: 640047KTOA) (CETIRIZINE UNII: Y07261ME24) CETIRIZINE HYDRO CHLO RIDE 10 mg

Inactive Ingredients		
Ingredient Name	Strength	
HYPROMELLOSES (UNII: 3NXW29V3WO)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
PO VIDO NE (UNII: FZ989 GH94E)		
STARCH, CORN (UNII: O8232NY3SJ)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

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

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				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA078343	12/17/20 18			

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

Revised: 12/2018 Dr. Reddy's Laboratories Inc.