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

Cetirizine Hydrochloride Tablets

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

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	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)

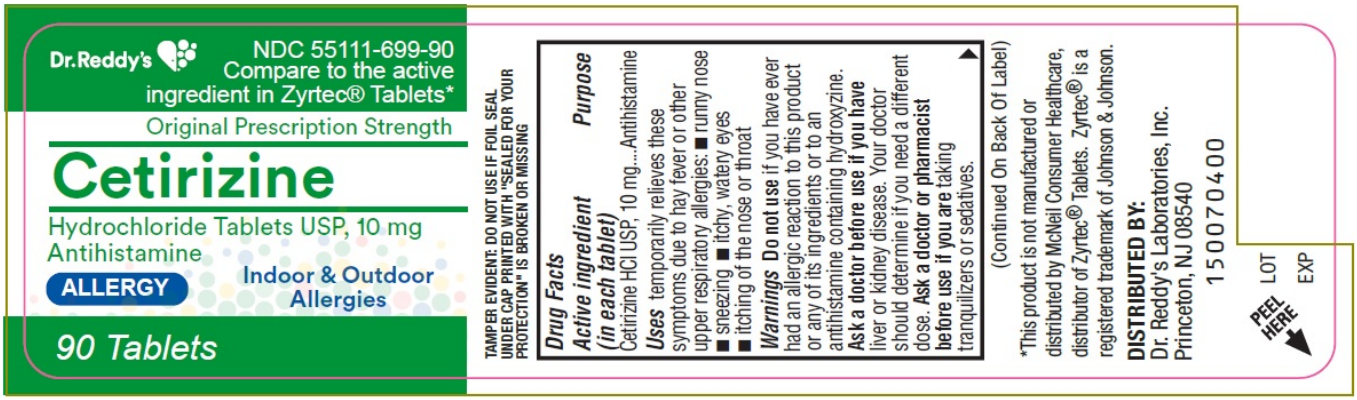
Inactive ingredients

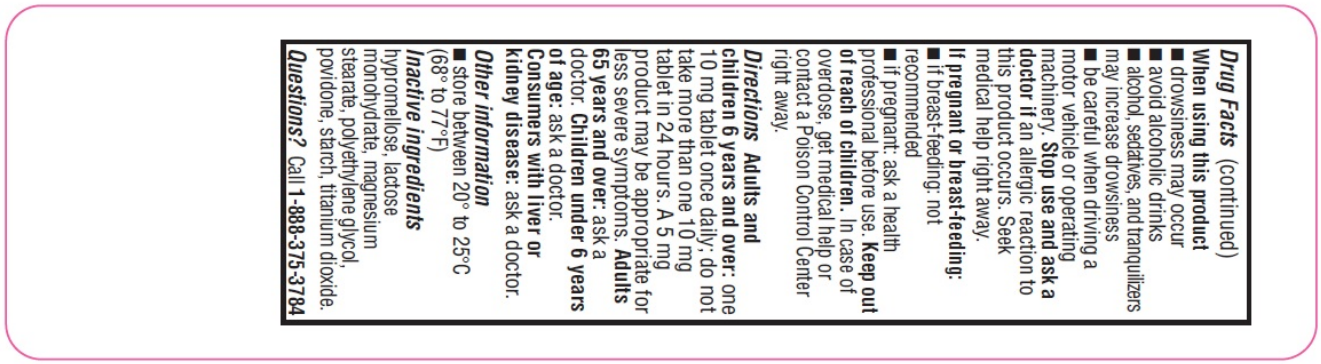
hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, starch, titanium dioxide.

Questions?

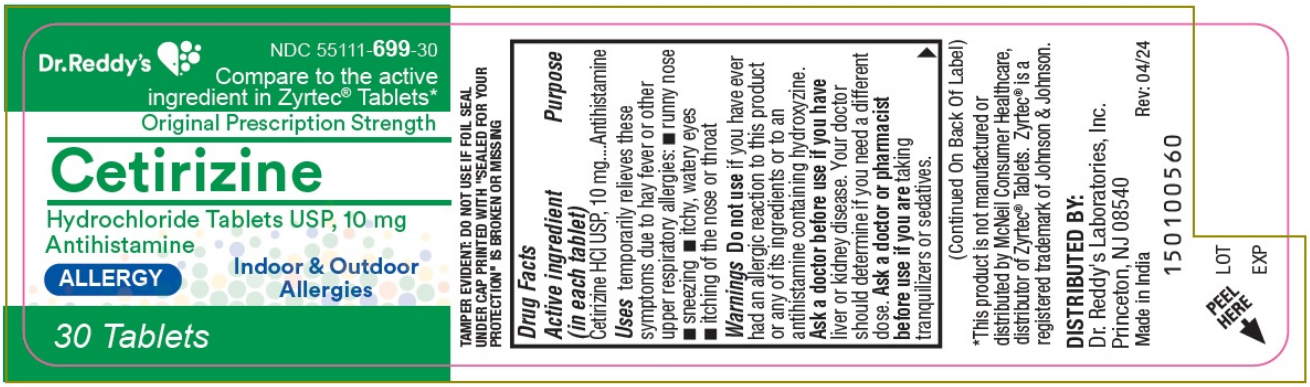
call **1-888-375-3784**.

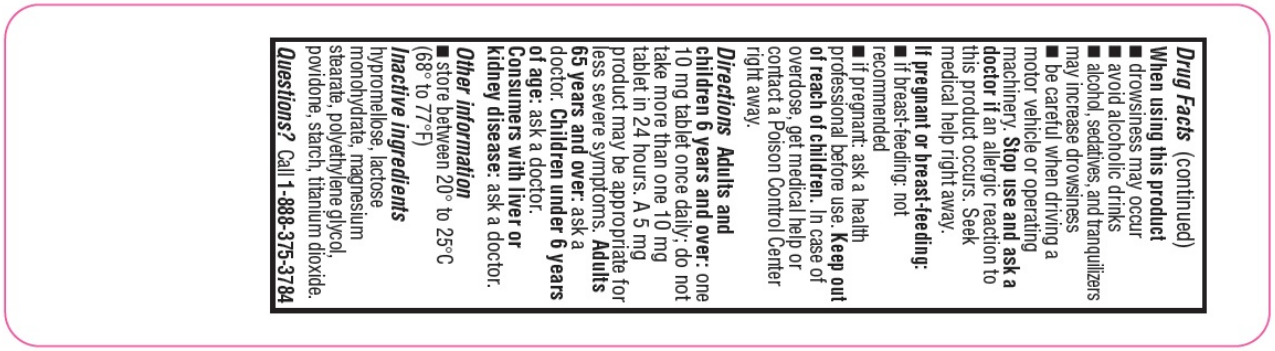
PACKAGE LABEL PRINCIPAL DISPLAY PANEL SECTION





PACKAGE LABEL PRINCIPAL DISPLAY PANEL SECTION





CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55111-699

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
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**	C
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-699-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2008	
2	NDC:55111-699-45	1 in 1 CARTON	04/08/2008	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55111-699-30	1 in 1 CARTON	04/03/2008	
3		30 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:55111-699-51	1 in 1 CARTON	07/22/2008	
4		75 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:55111-699-04	1 in 1 CARTON	04/11/2008	
5		120 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:55111-699-19	1 in 1 CARTON	01/15/2008	
6		175 in 1 BOTTLE; Type 0: Not a Combination Product		

7	NDC:55111-699-47	2 in 1 CARTON	04/03/2008	
7		175 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:55111-699-60	1 in 1 CARTON	04/07/2008	
8		60 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:55111-699-73	1 in 1 CARTON	10/06/2010	
9		365 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:55111-699-52	1 in 1 CARTON	10/06/2010	
10		14 in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:55111-699-74	2 in 1 CARTON	04/04/2008	
11		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
12	NDC:55111-699-31	1 in 1 CARTON	09/27/2016	
12		300 in 1 BOTTLE; Type 0: Not a Combination Product		
13	NDC:55111-699-15	1 in 1 CARTON	04/04/2008	
13		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078343	01/15/2008	

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55111-351
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
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	ROUND	**Size**	6mm
Flavor		**Imprint Code**	RDY;351
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-351-30	1 in 1 CARTON	01/15/2008	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55111-351-45	1 in 1 CARTON	01/15/2008	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55111-351-60	1 in 1 CARTON	01/15/2008	
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:55111-351-90	1 in 1 CARTON	01/15/2008	
4		90 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:55111-351-04	1 in 1 CARTON	01/15/2008	
5		120 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:55111-351-47	2 in 1 CARTON	01/15/2008	
6		175 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:55111-351-51	1 in 1 CARTON	01/15/2008	
7		75 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:55111-351-74	2 in 1 CARTON	01/15/2008	
8		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA078343	01/15/2008	

Labeler - Dr.Reddy's Laboratories Limited (650562841)

Revised: 9/2011 Dr.Reddy's Laboratories Limited