CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
TIME CAP LABORATORIES, INC.

682R Timely 49483-682 Cetirizine hydrochloride tablets USP 5 mg

DRUG FACTS

Active ingredient (in each tablet)

Cetirizine HCl 5 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	1 or 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.
adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in 24 hours.
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

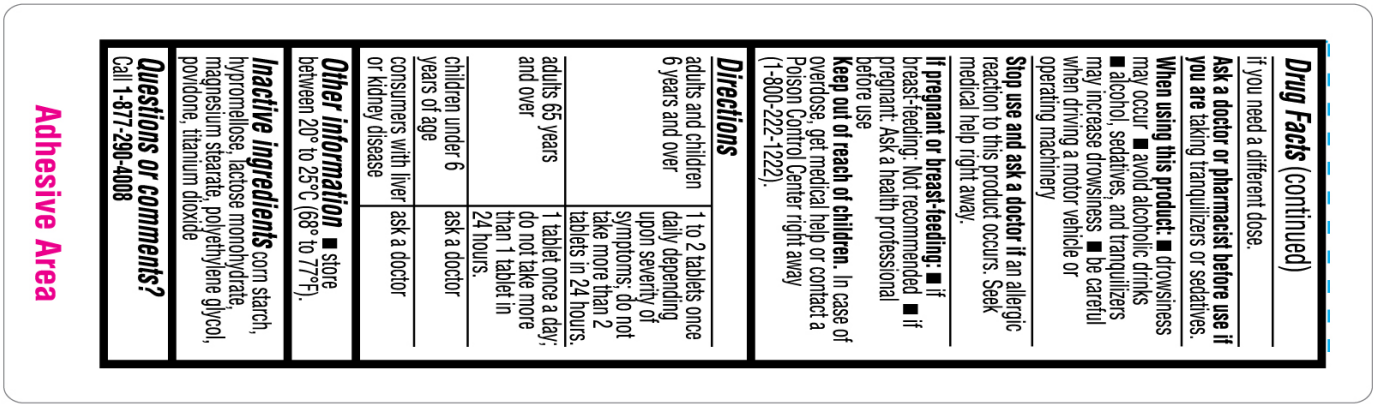
Other information

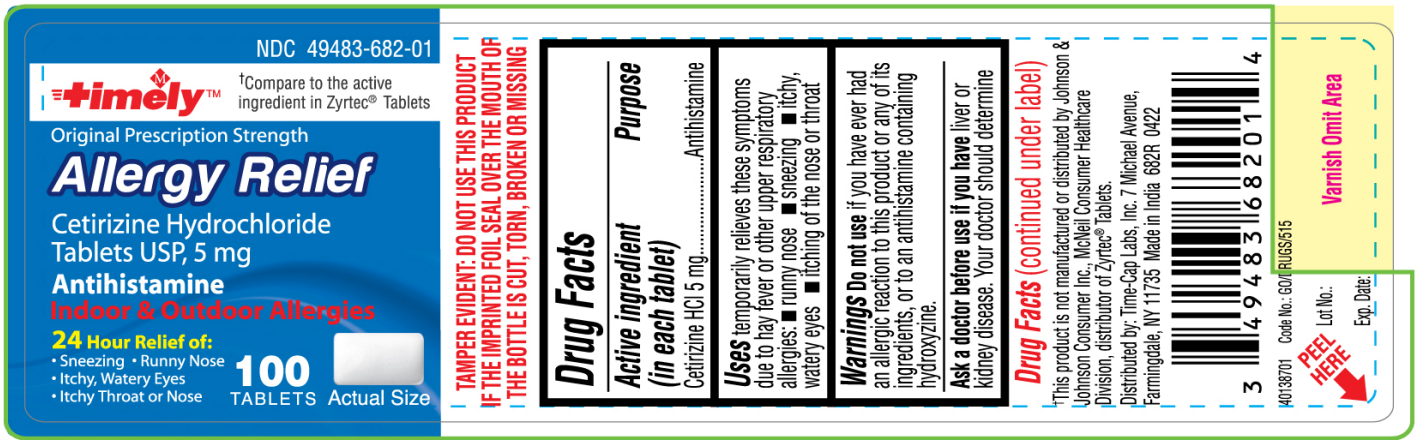
• store between 20° to 25°C (68° to 77°F).

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

Questions or comments?

Call **1-877-290-4008**





CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49483-682
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	white (White to off white)	**Score**	no score
Shape	RECTANGLE (Rounded-off rectangular shaped)	**Size**	7mm
Flavor		**Imprint Code**	J;219
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-682-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078933	05/30/2022	

Labeler - TIME CAP LABORATORIES, INC. (037052099)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-682)

Revised: 5/2022

TIME CAP LABORATORIES, INC.