CETIRIZINE HYDROCHLORIDE TABLETS,10 MG- cetirizine hydrochloride tablet
TIME CAP LABORATORIES, INC.

692R Timely Cetirizine hydrochloride tablets USP 10 mg

DRUG FACTS

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, 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	one 10 mg tablet once daily; do not take more than one 10 mg tablet

children 6 years and over	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, magnesium stearate, polyethylene glycol, povidone, titanium dioxide

Questions or comments?

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

Drug Facts (continued)

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Adhesive Area

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

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Drug Facts (continued under label)

Distributed by:
Time-Cap Labs, Inc.
7 Michael Avenue,
Farmingdale,
NY 11735
Made in India
4949R 0224

3 4 9 4 8 3 6 9 2 2 0 4

PEEL HERE

LOT:

EXP.:

Varnish Omit Area

NDC 49483-692-20

†Compare to the active ingredient in Zyrtec® Tablets

Timely™

Original Prescription Strength

Allergy Relief

Cetirizine Hydrochloride Tablets USP, 10 mg

Antihistamine

Indoor & Outdoor Allergies

24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

220

Actual Size

200 TABLETS

Adhesive Area

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Inside

NDC 49483-692-01

timely™

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Original Prescription Strength

Allergy Relief

Cetirizine Hydrochloride Tablets USP, 10 mg

Antihistamine

Indoor & Outdoor Allergies

24 Hour Relief of:
- Sneezing
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- Itchy, Watery Eyes
- Itchy Throat or Nose

220

100 TABLETS

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Drug Facts (continued under label)

†This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, owner of the registered trademark Zyrtec® Tablets

Distributed by: Time-Cap Labs, Inc.
17 Michael Avenue,
Farmingdale,
NY 11735

Made in India

692R 0224

3 49483 69201 3

PEEL HERE

LOT:

EXP.:

Varnish Omit Area

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Drug Facts (continued under label)

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Time-Cap Labs, Inc.
7 Michael Avenue,
Farmingdale,
NY 11735
Made in India
692R 0422

3 49483 69250 1

401386D1 Code No.: GO/DR/JGS/515

PEEL HERE

Lot No.:

Exp. Date:

Varnish Omit Area

NDC 49483-692-50

timely™

†Compare to the active ingredient in Zyrtec® Tablets

Original Prescription Strength

Allergy Relief

Cetirizine Hydrochloride Tablets USP, 10 mg

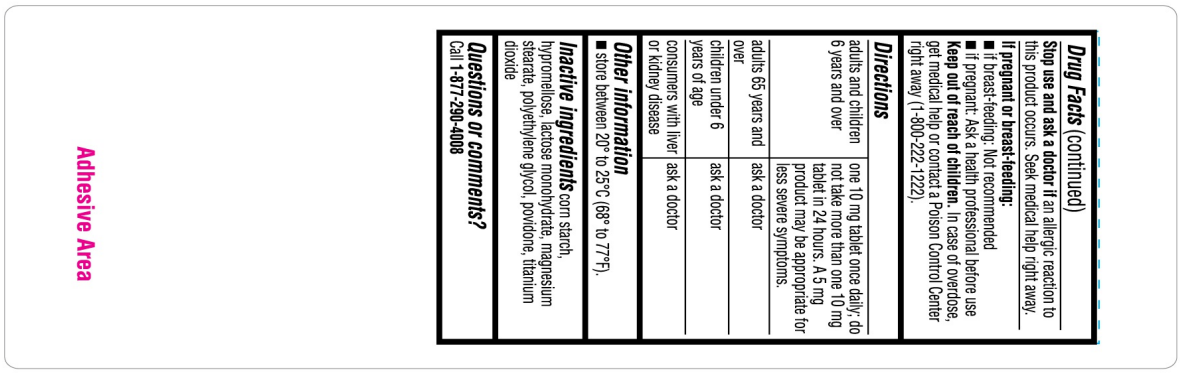
Antihistamine

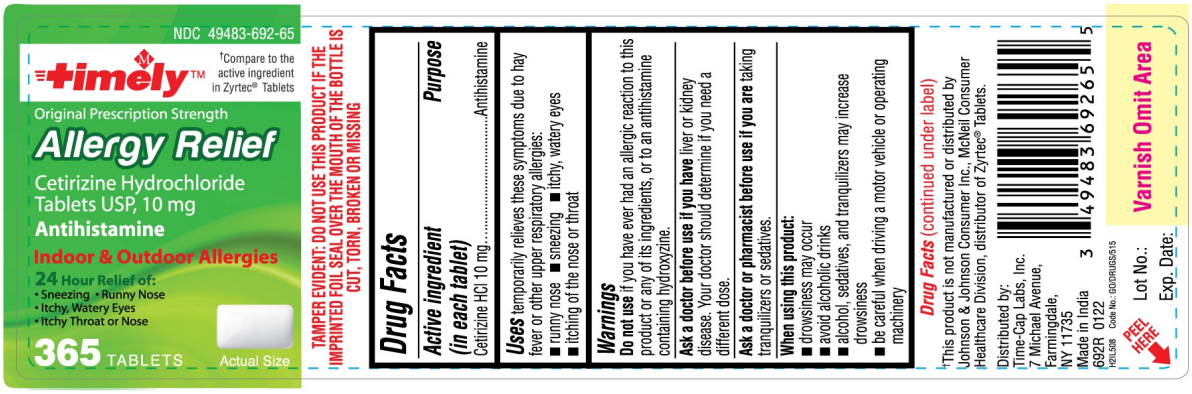
Indoor & Outdoor Allergies

24 Hour Relief of:
- Sneezing • Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

500 TABLETS

Actual Size





CETIRIZINE HYDROCHLORIDE TABLETS,10 MG

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49483-692
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**

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

Product Characteristics

Color	white (White to off white)	**Score**	no score
Shape	RECTANGLE (Rounded-off rectangular shaped)	**Size**	9mm
Flavor		**Imprint Code**	J;220
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-692-65	365 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2022	
2	NDC:49483-692-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2022	
3	NDC:49483-692-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/11/2024	
4	NDC:49483-692-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	03/11/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078933	02/12/2022	

Labeler - TIME CAP LABORATORIES, INC. (037052099)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-692)

Revised: 3/2024 TIME CAP LABORATORIES, INC.