# 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**

children 6 years and over symptoms.

adults 65 years and over children under 6 years of age consumers with liver or kidney in 24 hours. A 5 mg product may be appropriate for less severe symptoms.

ask a doctor

ask a doctor

ask a doctor

disease

#### 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** 

# Adhesive Area

I

I

I I

I

I

ı

I

# Other information store between 20° to 25°C (68° to 77°F)

Inactive ingredients corn starch,

consumers with liver or kidney disease

ask a doctor

children under 6

ask a doctor

years of age

adults 65 years and

ask a doctor

symptoms.

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

Directions

overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Keep out of reach of children. In case of

f **pregnant or breast-feeding** • If breast-feeding: not recommended • If pregnant ask a health professional before use

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

be careful when driving a motor vehicle or alcohol, sedatives, and tranquilizers may ■ drowsiness may occur
■ avoid alcoholic drinks

operating machinery increase drowsiness When using this product are taking tranquilizers or sedatives Ask a doctor or pharmacist before use if you

hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, titanium

Questions or comments? 1-877-290-4008

NDC 49483-692-20 <sup>†</sup>Compare to the active ingredient in Zyrtec® Tablets Relief llergy Cetirizine Hydrochloride Tablets USP, 10 mg Antihistamine Indoor & Outdoor Aller 24 Hour Relief of:
• Sneezing • Runny Nose
• Itchy, Watery Eyes
• Itchy Throat or Nose 20 0 TABLET:

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

Active ingredien in each tablet) *Drug Facts* 

Cetirizine HCl 10 mg.

Antihistamine

temporarily relieves these symptoms due to hay fever Uses

or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery itching of the nose or throat

Do not use if you have ever had an allergic reaction to Ask a doctor before use if you have liver or kidney this product or any of its ingredients, or to an antihistamine containing hydroxyzine

*Drug Fact*s (continued under label) disease. Your doctor should determine if you

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

LOT:

EXP.:



4

Drug

Facts (continued

need a different dose

Varnish Omit Area

#### 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). children under 6 years of age 6 years and over Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away. Questions or comments? monohydrate, magnesium stearate, polyethylene glycol, povidone, titanium Inactive ingredients com starch, hypromellose, lactose or kidney disease over adults 65 years and Directions Drug Facts (continued consumers with liver adults and children be careful when driving a motor vehicle Other information ■ store between 20° to 25°C (68° to 77°F) When using this product pregnant or breast-feeding If breast-feeding: not recommended If pregnant: ask a health professional or operating machinery alcohol, sedatives, and tranquilizers may drowsiness may occur avoid alcoholic drinks increase drowsiness Adhesive Area one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg ask a doctor ask a doctor ask a doctor product may be appropriate for less severe symptoms.

# Inside



Varnish Omit Area

692R 0224

Made in India

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

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

*Drug Facts* (continued under label

Ask a doctor or pharmacist before use if you are

different dose

taking tranquilizers or sedatives.

FXP.:

Adhesive Area

#### children under 6 years of age If pregnant or breast-feeding: if breast-feeding: Not recommended fregnant. 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). Other information ■ store between 20° to 25°C (68° to 77°F). adults and children 6 years and over **Stop use and ask a doctor if** an allergic reaction to this product occurs. Seek medical help right away. consumers with liver or kidney disease Drug Facts (continued) glycol, povidone, titanium dioxide actose monohydrate, magnesium stearate, polyethylene Inactive ingredients corn starch, hypromellose adults 65 years and 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 ask a doctor ask a doctor ask a doctor less severe symptoms.

Questions or comments? Call 1-877-290-4008

Purpose Antihistamine

Active ingredient

(in each tablet) Cetirizine HCI 10 mg....

Uses



<sup>1</sup>This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, distributor of Zyrtec® Tablets. 0 Varnish Omit Area Ŋ Drug Facts (continued under label) 0 9 M 4 8 4 9 Code No.: GO/DR JGS/515 3 Lot No.: Distributed by: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735 Made in India 692R 0422 40138601

drowsiness

• be careful when driving a motor vehicle or operating

When using this product: drowsiness may occuravoid alcoholic drinks

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose. **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 or pharmacist before use if you are taking tranquilizers or sedatives.

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

= unny nose = sneezing = itchy, watery eyes = itching of the nose or fitnoat

Warnings

■ alcohol, sedatives, and tranquilizers may increase

Exp. Date:

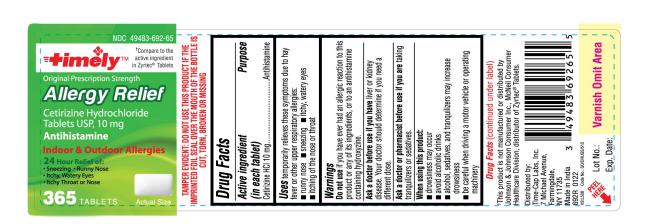












consumers with liver a or kidney disease

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 stearate, polyethylene glycol, povidone, titanium

**Questions or comments?** Call 1-**8**77-290-4008 adults 65 years and over children under 6 years of age

ask a doctor

less severe symptoms.

■ 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).

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

pregnant or breast-feeding:

Drug Facts (continued)

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

Directions

### **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	<b>Basis of Strength</b>	Strength		
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZ INE 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: 3WJQ0SDW1A)	

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				

P	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	<b>Business Operations</b>		
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-692)		

Revised: 3/2024 TIME CAP LABORATORIES, INC.