CETIRIZINE HYDROCHLORIDE 10 MG- cetirizine hydrochloride tablet TWIN MED, LLC

TWIN MED - PROCURE - CETIRIZINE HYDROCHLORIDE TABLETS, 10 MG (55681-302)

Active ingredient (in each tablet)

Cetirizine Hydrochloride 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 children One 10 mg tablet once daily; do not take more than one 10mg **6 years of age and** tablet in 24 hours. A 5mg product may be appropriate for less severe symptoms.

adults 65 years

and older

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° and 25°C (68° and 77°F)

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Questions?

call toll-free 1-800-935-6737



DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

Active ingredient (in each tablet)

Purpose

Cetirizine hydrochloride 10 mg......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

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- if breast-feeding: not recommended
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■ PEEL FOR DIRECTIONS

G7032-300-108-0

Drug Facts (continued)

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 ohildren 6 years of age 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
oonsumers with liver or kidney disease	ask a doctor

Other information

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

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

Questions? call toll-free 1-800-935-6737

*This product is not manufactured or distributed by the owner of the registered trademark Zyrtec®

Distributed by: ProCure Products

11333 Greenstone Avenue Santa Fe Springs, CA 90670

ITEM# PCOTC126

CETIRIZINE HYDROCHLORIDE 10 MG

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55681-302
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE	10 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	white	Score	2 pieces
Shape	RECTANGLE (ROUNDED)	Size	10mm
Flavor		Imprint Code	G4
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:55681-302- 03	300 in 1 BOTTLE; Type 0: Not a Combination Product	03/02/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209274	03/02/2022	

Labeler - TWIN MED, LLC (009579330)

Revised: 1/2024 TWIN MED, LLC