CETIRIZINE- cetirizine hydrochloride tablet, film coated Aphena Pharma Solutions - Tennessee, LLC

Major Pharmaceuticals Cetirizine 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 children 6 years and	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24
over	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	ask a doctor
disease	

Other information

- store between 20-25°C (68-77°F)
- do not use if printed foil under cap is broken or missing

Inactive ingredients

corn starch, FD&C blue no. 1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin

Questions or comments?

1-800-719-9260

Repackaging Information

Please reference the *How Supplied* section listed above for a description of individual tablets. This drug product has been received by Aphena Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphena are listed below:

Count	10 mg
90	71610-123-60

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:

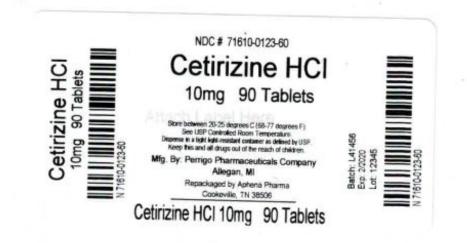


Cookeville, TN 38506

20180905JH

PRINCIPAL DISPLAY PANEL - 10 mg

NDC 71610-123 - Cetirizine HCl 10 mg - Rx Only



CETIRIZINE					
cetirizine hydrochloride tablet	, film coated				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:71610-123(NDC:0904-6717)			
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
	Ingredient Name		Basis of Strength	Strength	
CETIRIZINE HYDRO CHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII: Y07261ME24)			CETIRIZINE HYDROCHLORIDE	10 mg	
Inactive Ingredients					
Ingredient Name				Strength	
STARCH, CORN (UNII: 08232NY	/3SJ)				
FD&C BLUE NO. 1 (UNII: H3R47)	K3TBD)				
HYPROMELLOSE, UNSPECIFIE	ED (UNII: 3NXW29V3WO)				
LACTOSE MONOHYDRATE (UI	NII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII:	70097M6I30)				
	U12IE)				
POLYDEXTROSE (UNII: VH2XO		'1A)			
POLYETHYLENE GLYCOL, UN	SPECIFIED (UNII: 3WJQ0SDW				
,					
POLYETHYLENE GLYCOL, UN	I: FZ989GH94E)				

Product Charac	cteristics						
Color		WHITE	Score		ne	no score	
Shape		OVAL	Size		10	10 mm	
Flavor			Imprint Code		4]	4H2	
Contains							
Packaging							
# Item Code		Package Desc	cription		Marketing Start Date	Marketing End Date	
1 NDC:71610-123- 60	90 in 1 BC Product	OTTLE, PLASTIC; Type (): Not a Combination	08	/17/2018		
Marketing Ir	nformat	ion					
	orv App	lication Number or N	Anograph Citation	Mar	keting Start Date	Marketing End Date	
Marketing Catego	- J II		01				

Labeler - Aphena Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-123)

Revised: 12/2019

Aphena Pharma Solutions - Tennessee, LLC