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

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#### **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:

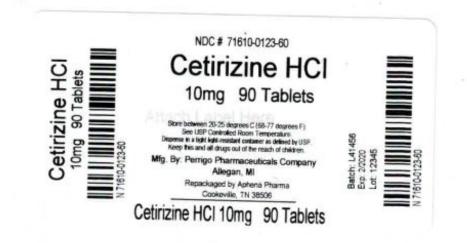


Cookeville, TN 38506

20180905JH

# **PRINCIPAL DISPLAY PANEL - 10 mg**

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



CETIRIZINE					
cetirizine hydrochloride tablet	, film coated				
<b>Product Information</b>					
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)				

<b>Product Charac</b>	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	<b>Business Operations</b>
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-123)

Revised: 12/2019

Aphena Pharma Solutions - Tennessee, LLC