

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, chewable**  
**Wal-Mart Stores, Inc.**

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**Equate**

**Cetirizine Hydrochloride Chewable Tablets 10 mg**

**Active Ingredient in each chewable tablet**

Cetirizine Hydrochloride Chewable Tablets 10mg

**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 reactions 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 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 the reach of children

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

## Directions

- may be taken with or without water

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 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)
- Do not use if individual blister unit is open or torn

## Inactive Ingredients

acesulfame potassium, colloidal silicon dioxide, D&C YELLOW # 10, FD&C RED # 40, FD&C YELLOW # 6, low substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polacrilex resin, sodium starch glycolate, sucralose and tutti frutti flavor

## QUESTIONS

1-888-287-1915

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 49035-652-25

**Children's  
Cetirizine HCl Chewable Tablet**

**10 mg** antihistamine

Distributed by: Wal-Mart Stores, Inc.  
Bentonville, AR 72716



N 3 49035-652-25 0

Lot # Exp.

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## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, chewable

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-652
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
POLACRILIN (UNII: RCZ785HI7S)	

ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics			
Color	YELLOW	Score	no score
Shape	ROUND	Size	10 mm
Flavor	TUTTI FRUTTI	Imprint Code	n;10
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-652-24	4 in 1 CARTON	03/08/2016	
1	NDC:49035-652-25	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206793	03/08/2016	

**Labeler** - Wal-Mart Stores, Inc. (051957769)

**Registrant** - Novel Laboratories, Inc. (793518643)

Establishment			
Name	Address	ID/FEI	Business Operations
Novel Laboratories, Inc.		793518643	ANALYSIS(49035-652) , MANUFACTURE(49035-652) , PACK(49035-652)