# 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

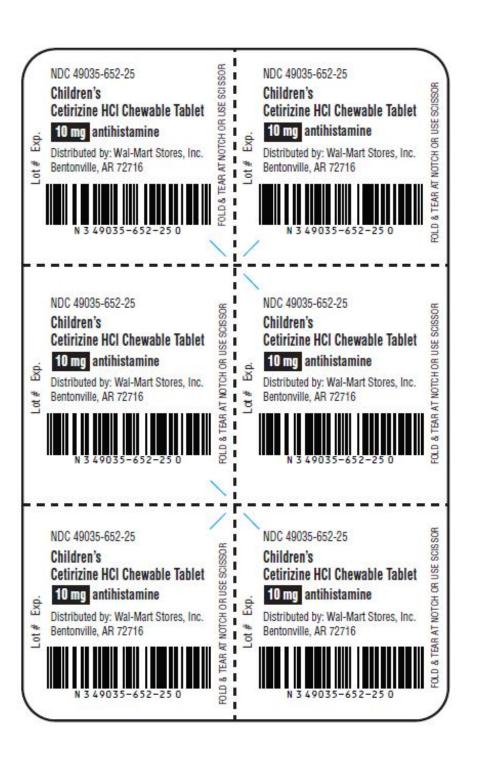
## **Inactive Ingredients**

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





## **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 HYDRO CHLO RIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII: YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients		
Ingredient Name	Strength	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
HYDRO XYPRO PYL CELLULO SE, LOW SUBSTITUTED (UNII: 2165RE0 K14)		
POLACRILIN (UNII: RCZ785HI7S)		

ACESULFAME POTASSIUM (UNII: 230 V73Q5G9)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
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			

l	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 NDC:49035-652-24	4 in 1 CARTON	03/08/2016	
l	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)

Revised: 12/2018 Wal-Mart Stores, Inc.