CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, chewable
Novel Laboratories, Inc.

Cetirizine Hydrochloride Chewable Tablets

Active Ingredient in each chewable tablet

For 5 mg:

Cetirizine hydrochloride 5 mg

For 10 mg:

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 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

For Cetirizine Hydrochloride Chewable Tablets, 5 mg

adults and children 6 years and over	1 to 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.
adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in 24 hours
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

For Cetirizine Hydrochloride Chewable Tablets, 10 mg

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

Call **1-866-403-7592**

Manufactured by:

Novel Laboratories, Inc.

Somerset, NJ 08873

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

For 5 mg Allergy:

NDC 40032-653-03

Children's

Cetirizine Hydrochloride Chewable Tablets

5 mg

ALLERGY

Antihistamine

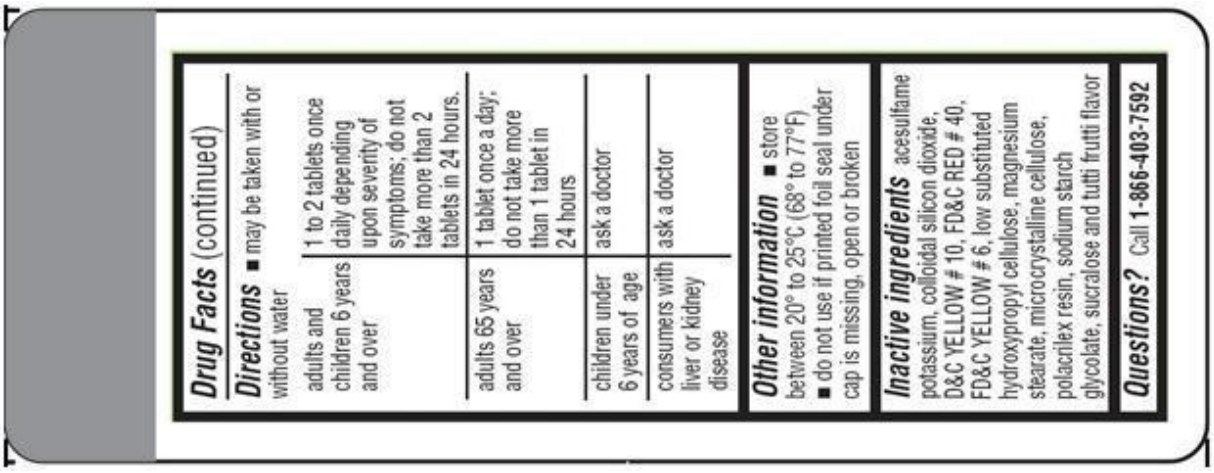
Indoor & Outdoor Allergies

Tutti-frutti Flavor

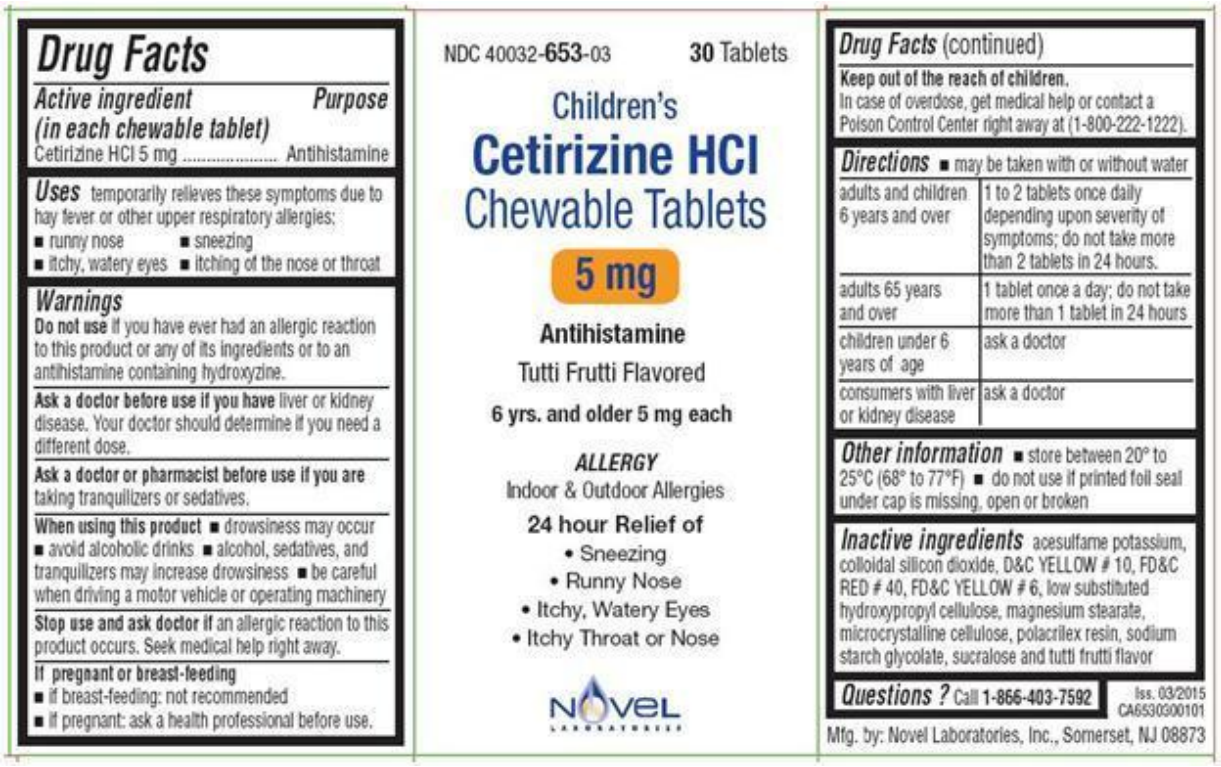
6 yrs. & older

30 CHEWABLE TABLETS

Container Label



Container Carton



For 10 mg Allergy:

NDC 40032-652-31

Children's

Cetirizine Hydrochloride Chewable Tablets

10 mg

ALLERGY

Antihistamine

Indoor & Outdoor Allergies

Tutti-frutti Flavor

6 yrs. & older

Blister Label

Blister Carton

NDC 40032-652-30

Drug Facts

Active ingredient (in each chewable tablet) Purpose
Cetirizine HCl 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
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 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.

Drug Facts (continued)

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? Call 1-866-403-7592

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:40032-653
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 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**	7mm
Flavor	TUTTI FRUTTI	**Imprint Code**	n;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40032-653-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/08/2016	
2	NDC:40032-653-30	3 in 1 CARTON	03/08/2016	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:40032-653-03	1 in 1 CARTON	03/08/2016	
3		30 in 1 BOTTLE; 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	

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:40032-652
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**	10mm
Flavor	TUTTI FRUTTI	**Imprint Code**	n;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40032-652-30	3 in 1 CARTON	03/08/2016	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:40032-652-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/08/2016	
3	NDC:40032-652-03	1 in 1 CARTON	03/08/2016	
3		30 in 1 BOTTLE; 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 - Novel Laboratories, Inc. (793518643)

Registrant - Novel Laboratories, Inc. (793518643)

Establishment

Name	Address	ID/FEI	Business Operations
Novel Laboratories, Inc.		793518643	analysis(40032-653, 40032-652) , manufacture(40032-653, 40032-652)

Revised: 12/2019 Novel Laboratories, Inc.