

CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet, chewable
Jubilant Cadista Pharmaceuticals Inc.

Children's
Cetirizine Hydrochloride Chewable Tablets
Antihistamine

DRUG FACTS

Active Ingredient (in each chewable tablet)

Cetirizine Hydrochloride 5 mg

Cetirizine Hydrochloride 10 mg

Purpose

Antihistamine

Uses:

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- 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 at (1-800-222-1222).

Directions:

- may be taken with and 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)
- **Phenylketonurics:** Contains 1.68 mg Phenylalanine (a component of Aspartame) per 5 mg
- **Phenylketonurics:** Contains 3.36 mg Phenylalanine (a component of Aspartame) per 10 mg
- **do not use if carton is opened or if blister unit is broken.**
- see bottom panel for lot number and expiration date.

Inactive ingredients:

acesulfame potassium, artificial and natural flavors, aspartame, betadex, colloidal silicon dioxide, croscarmellose sodium, dl-alpha-tocopherol, ethyl cellulose, FD&C yellow # 6 aluminum lake, fumaric acid, hypromellose, magnesium stearate, mannitol, maltodextrin, microcrystalline cellulose and talc.

Questions? call 1-800-313-4623

Manufactured by:

Jubilant Generics Ltd.
Roorkee-247661, India

Marketed by:

Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA

Revised : November / 2014

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

CADISTA

NDC 59746-285-32

Children's

**Cetirizine Hydrochloride Chewable Tablets 5 mg
Antihistamine**

ALLERGY

Phenylketonurics: contains 1.68 mg Phenylalanine (a component of Aspartame) per 5 mg tablets.

Indoor & Outdoor Allergies

24 hour Relief of

- Sneezing
- Running Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

TAMPER EVIDENT : Do not use if blister unit is broken or torn.

6 yrs. & older

5 mg each

30 Chewable Tablets

5 mg each

Orange Chewables



CADISTA

NDC 59746-286-32

Children's

**Cetirizine Hydrochloride Chewable Tablets 10 mg
Antihistamine**

ALLERGY

Phenylketonurics: contains 3.36 mg Phenylalanine (a component of Aspartame) per 10 mg tablets.

Indoor & Outdoor Allergies

24 hour Relief of

- Sneezing
- Running Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

TAMPER EVIDENT : Do not use if blister unit is broken or torn.

6 yrs. & older
10 mg each

30 Chewable Tablets **Orange Chewables**
10 mg each



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59746-285
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
Acesulfame Potassium (UNII: 23OV73Q5G9)	
Aspartame (UNII: Z0H242BBR1)	
Betadex (UNII: JV039JZZ3A)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
.alpha.-tocopherol, DI- (UNII: 7QWA1RIO01)	
Ethylcelluloses (UNII: 7Z8S9VYZ4B)	
Fd&c Yellow No. 6 (UNII: H77VEI93A8)	
Fumaric Acid (UNII: 88XHZ13131)	
Hypromelloses (UNII: 3NXW29V3WO)	
Magnesium Stearate (UNII: 70097M6I30)	
Mannitol (UNII: 3OWL53L36A)	
Maltodextrin (UNII: 7CVR7L4A2D)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Talc (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	8 mm
Flavor	ORANGE	Imprint Code	C285
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59746-285-32	3 in 1 CARTON	02/19/2015	
1		10 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	ANDA091116	02/19/2015	

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59746-286
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
Acesulfame Potassium (UNII: 23OV73Q5G9)	
Aspartame (UNII: Z0H242BBR1)	
Betadex (UNII: JV039JZZ3A)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
.alpha.-tocopherol, DI- (UNII: 7QWA1RIO01)	
Ethylcelluloses (UNII: 7Z8S9VYZ4B)	
Fd&c Yellow No. 6 (UNII: H77VEI93A8)	
Fumaric Acid (UNII: 88XHZ13131)	
Hypromelloses (UNII: 3NXW29V3WO)	
Magnesium Stearate (UNII: 70097M6I30)	
Mannitol (UNII: 3OWL53L36A)	
Maltodextrin (UNII: 7CVR7L4A2D)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Talc (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	11mm
Flavor	ORANGE	Imprint Code	C286
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59746-286-32	3 in 1 CARTON	02/19/2015	
1		10 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	ANDA091116	02/19/2015	

Labeler - Jubilant Cadista Pharmaceuticals Inc. (022490515)

Registrant - Jubilant Generics Limited (650801538)

Establishment

Name	Address	ID/FEI	Business Operations
Jubilant Generics Limited Roorkee		650369221	MANUFACTURE(59746-285, 59746-286)

Revised: 12/2019

Jubilant Cadista Pharmaceuticals Inc.