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:

relieves itching due to hives (urticaria).

This product will not prevent hives or an allergic skin reaction from occurring.

Warnings:

Severe Allergy Warning: Get emergency help immediately if you have hives along with any of the following symptoms:

- trouble swallowing
- swelling of tongue
- trouble speaking
- wheezing or problems breathing
- dizziness or loss of conciousness
- swelling in or around mouth
- drooling

These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by health professional **immediately.** Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use

- to **prevent** hives from any known cause such as:
- foods
- insect stings
- medicines

- latex or rubber gloves

because this product will not stop hives from occuring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious.

If you do not know the cause of your hives, see your doctor for a medical exam.

Your doctor may be able to help you find a cause.

- 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.
- hives that are an unusual color, look bruised or blistered.
- hives that do not itch.

Ask a doctor or pharmacist before use if you are taking transquillizers 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
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

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

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 20º to 25º C (68º to 77º 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 & 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 59746-285-33**

Children's
Cetirizine Hydrochloride Chewable Tablets 5 mg
Antihistamine

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

HIVES Relief
24 hour Relief of Itching due to hives

6 yrs. & older 5 mg each

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

30 Chewable Tablets
5 mg each

Orange Chewables

Cetirizine Hydrochloride Chewable Tablets 5 mg Hives Relief

CADISTA **NDC 59746-286-33**

Children's
Cetirizine Hydrochloride Chewable Tablets 10 mg
Antihistamine

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

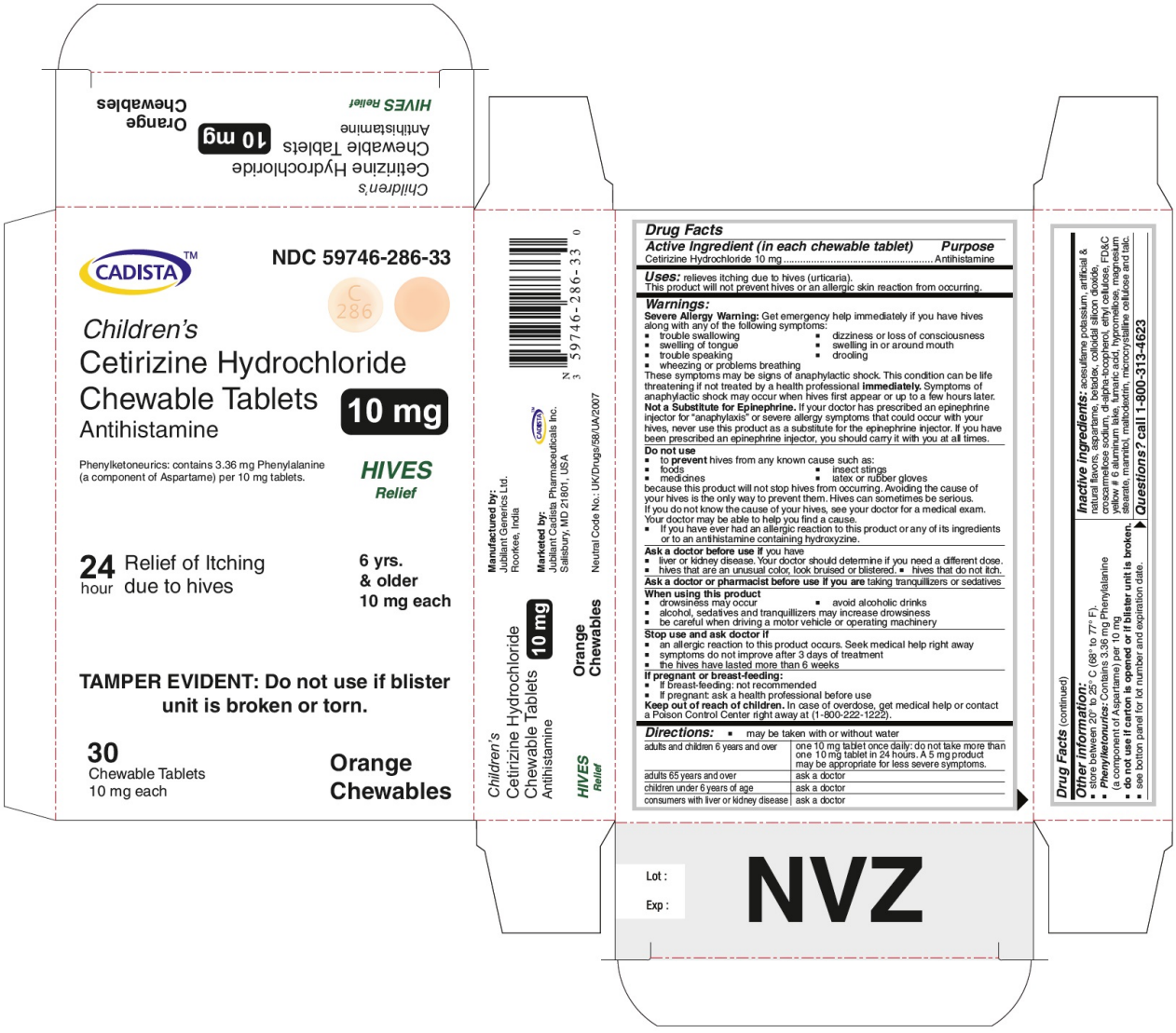
HIVES Relief
24 hour Relief of Itching due to hives

6 yrs. & older 10 mg each

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

30 Chewable Tablets
10 mg each

Orange Chewables



Cetirizine Hydrochloride Chewable Tablets 10 mg Hives Relief

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, Dl- (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**	8mm
Flavor	ORANGE	**Imprint Code**	C285
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59746-285-33	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, Dl- (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:59746-286-33	3 in 1 CARTON	12/19/2015	
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.