CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet, chewable
Chain Drug Consortium, LLC

Cetirizine Hydrochloride Chewable Tablets

Active ingredient (in each chewable tablet)

Cetirizine hydrochloride, USP 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 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. (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 inner safety seal is open or torn
- see top layer for lot number and expiration date

Inactive ingredients

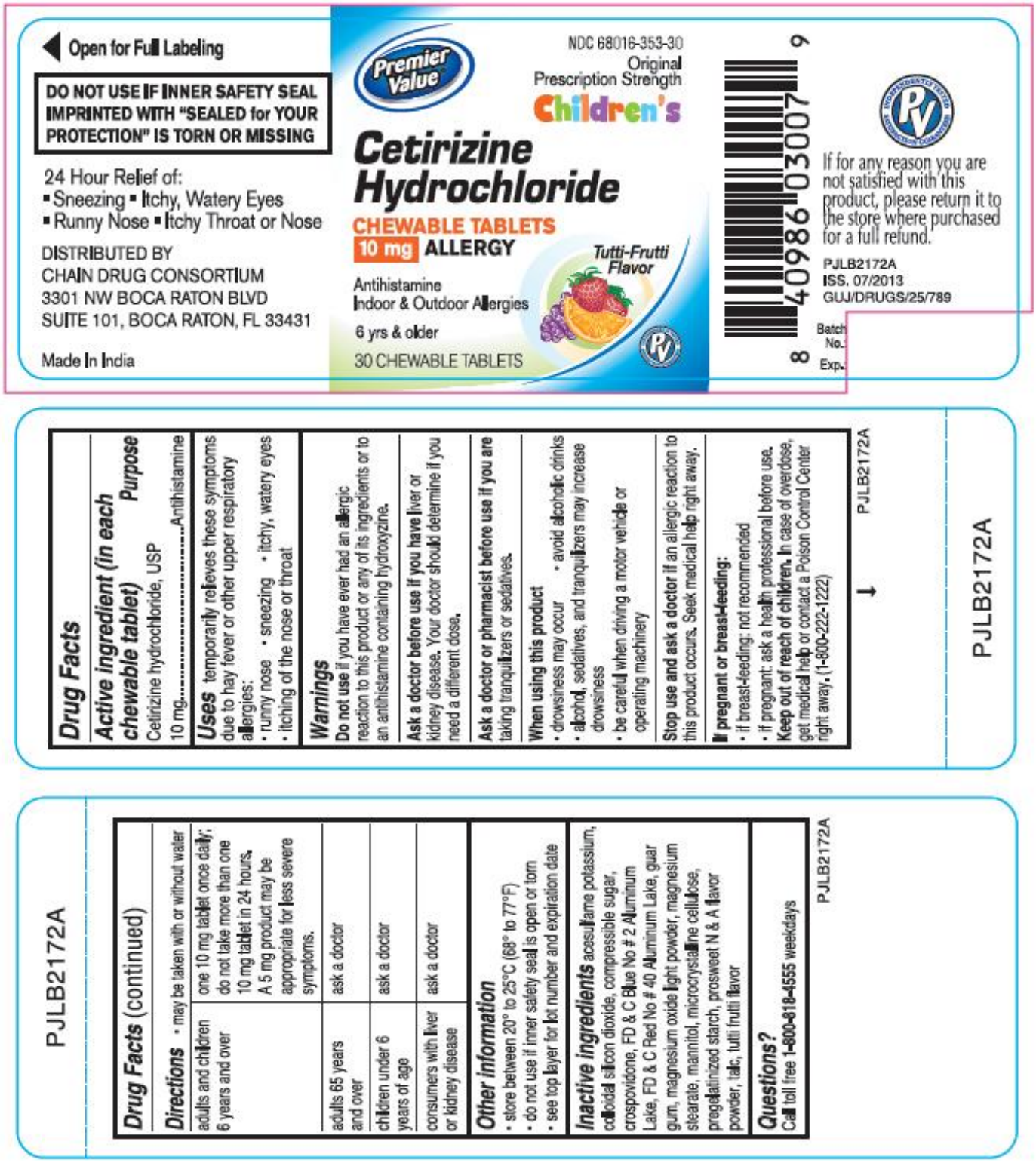
acesulfame potassium, colloidal silicon dioxide, compressible sugar, crospovidone, FD & C Blue No # 2 Aluminum Lake, FD & C Red No # 40 Aluminum Lake, guar gum, magnesium oxide light powder, magnesium stearate, mannitol, microcrystalline cellulose, pregelatinized starch, prosweet N & A flavor powder, talc, tutti frutti flavor

Questions?

Call toll free **1-800-818-4555** weekdays

Principal Display Panel

NDC 68016-353-30
Original Prescription Strength
Children's
Cetirizine Hydrochloride
CHEWABLE TABLETS
10 mg
ALLERGY
Antihistamine
Indoor & Outdoor Allergies
Tutti-frutti Flavor
6 yrs & older
30 CHEWABLE TABLETS



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-353
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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCROSE (UNII: C151H8M554)	
CROSPOVIDONE (UNII: 68401960MK)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GUAR GUM (UNII: E89I1637KE)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	PURPLE	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor	TUTTI FRUTTI	**Imprint Code**	344
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-353-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090142	09/10/2013	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - Sun Pharmaceutical Industries Limited (650172430)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		725959238	MANUFACTURE(68016-353)