CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
DIRECT RX

Cetirizine Hydrochloride

OTC - ACTIVE INGREDIENT SECTION

Active Ingredients (in each tablet) Purpose

Cetirizine HCl 10 mg.....Antihistimine

OTC - PURPOSE SECTION

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 SECTION

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.

OTC - ASK DOCTOR SECTION

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

OTC - ASK DOCTOR/PHARMACIST SECTION

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

OTC - WHEN USING SECTION

- drowsines may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinary

INDICATIONS & USAGE SECTION

drowsines may occur
avoid alcoholic drinks
alcohol, sedatives, and tranquilizers may increase drowsiness
be careful when driving a motor vehicle or operating machinary.

OTC - STOP USE SECTION

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

OTC - PREGNANCY OR BREAST FEEDING SECTION

- if breast-feeding: not recommended
- if pregnant: ask a health professional before use.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

In case of overdose, get medical help or contact Poison Control Center right away.

INSTRUCTIONS FOR USE SECTION

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 sever 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

DOSAGE & ADMINISTRATION SECTION

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 sever 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 SAFETY INFORMATION

store between 20° to 25°C (68° to 77°F)

INACTIVE INGREDIENT SECTION

Hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide.

OTC - QUESTIONS SECTION

Call 1-866-562-4597

SPL UNCLASSIFIED SECTION

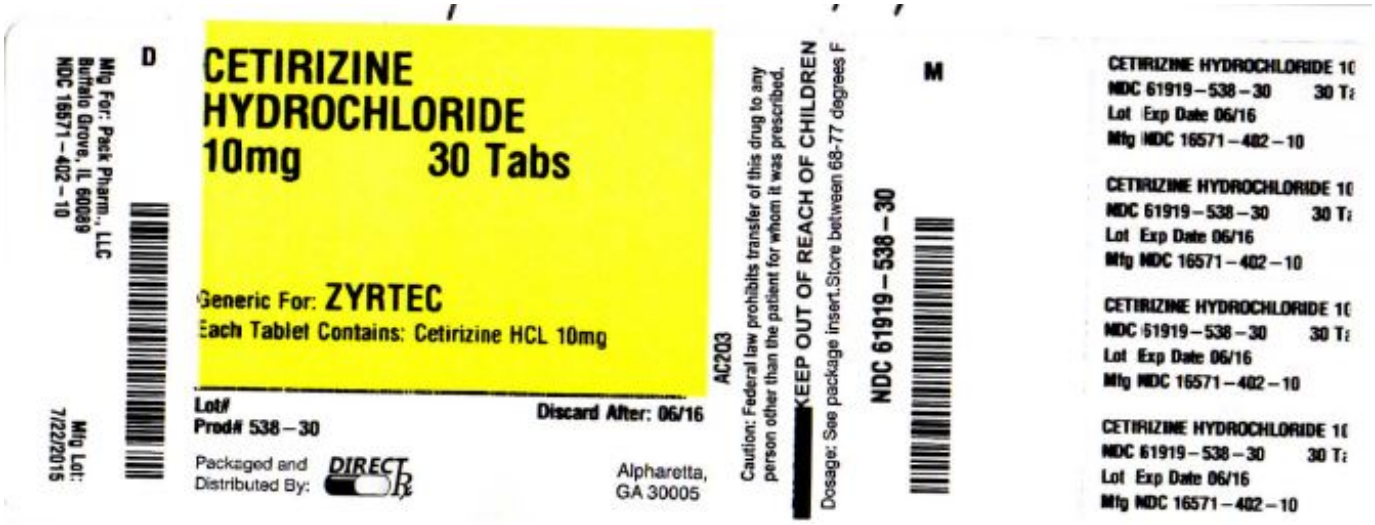
Manufactured for PACK Pharmaceuticals, LLC

Buffalo Grove, IL 60089, USA

Manufactured by Unique Pharmaceutical Laboratories (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.),

Mumbai 400 030, India

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-538(NDC:16571-402)
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**
hypromelloses (UNII: 3NXW29V3WO)	
lactose (UNII: J2B2A4N98G)	
magnesium stearate (UNII: 70097M6I30)	
starch, corn (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
povidone (UNII: FZ989GH94E)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	BULLET	**Size**	8mm
Flavor		**Imprint Code**	CTN;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-538-30	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	ANDA077829	01/01/2014	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	relabel(61919-538) , repack(61919-538)

Revised: 11/2015 DIRECT RX