CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
H. J. Harkins Company Inc.

Active Ingredient

(in each tablet)

Cetirizine HCl 10 mg

Purpose

Antihistamine

Keep out of Reach of Children

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

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

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

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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.

Directions

dults 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

Inactive Ingredient

Corn starch, hypromellose, lactose monohydrate, macrogol, magnesium stearate, povidone and titanium dioxide.

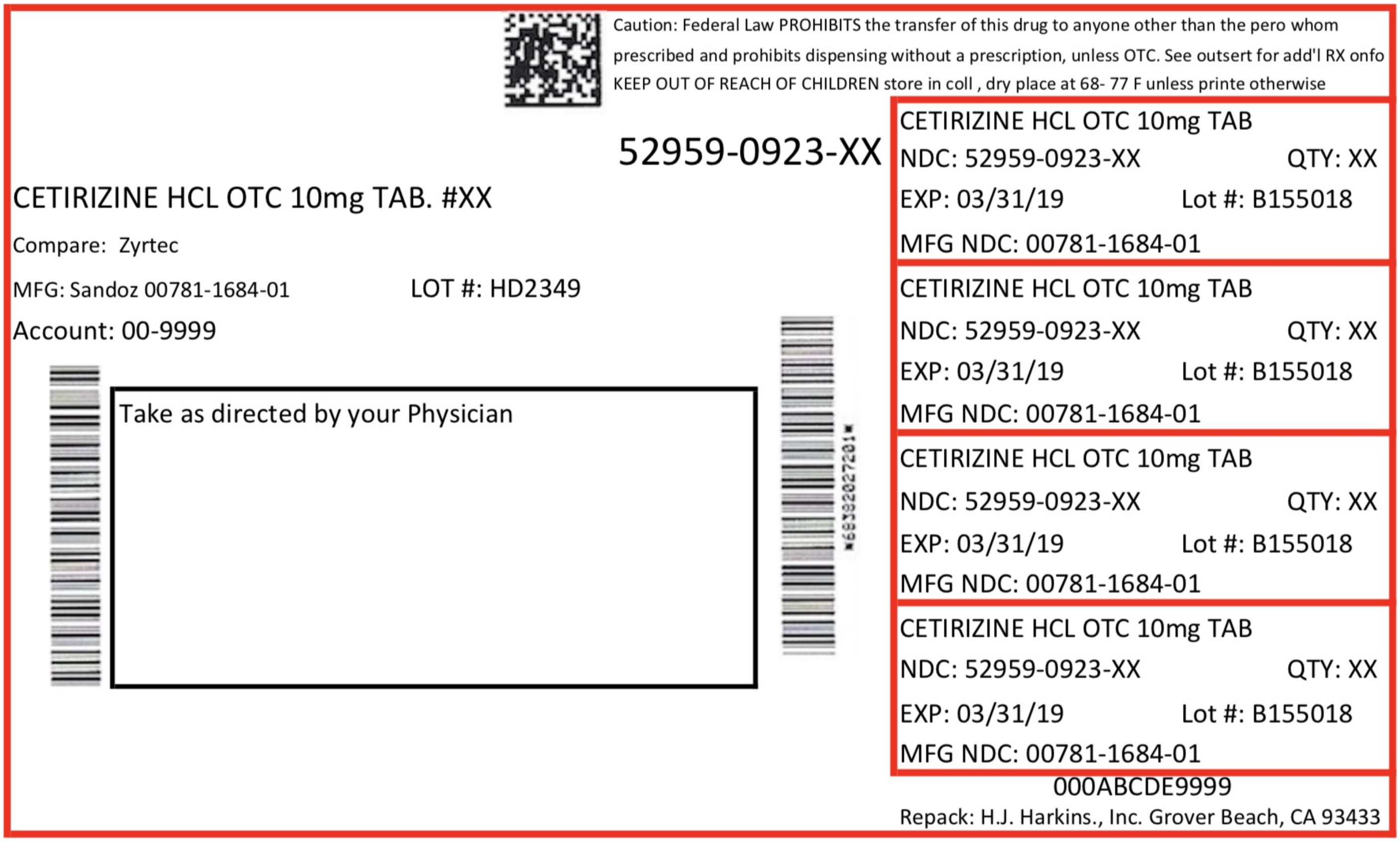
Questions? 1-800-525-8747

Manufactured in India by Sandoz Private Ltd.,

for Sandoz Inc., Princeton, NJ 08540

Rev.06/2013

Package Label. Principal Display Panel



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52959-923
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

Product Characteristics

Color	white	**Score**	score with uneven pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	SZ;906
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-923-10	10 in 1 CONTAINER; Type 0: Not a Combination Product	01/03/2017	
2	NDC:52959-923-15	15 in 1 CONTAINER; Type 0: Not a Combination Product	01/03/2017	

3	NDC:52959-923-30	30 in 1 CONTAINER; Type 0: Not a Combination Product	01/03/2017	
4	NDC:52959-923-60	60 in 1 CONTAINER; Type 0: Not a Combination Product	01/03/2017	
5	NDC:52959-923-90	90 in 1 CONTAINER; Type 0: Not a Combination Product	01/03/2017	
6	NDC:52959-923-07	7 in 1 CONTAINER; Type 0: Not a Combination Product	01/03/2017	
7	NDC:52959-923-20	20 in 1 CONTAINER; Type 0: Not a Combination Product	01/03/2017	
8	NDC:52959-923-14	14 in 1 CONTAINER; Type 0: Not a Combination Product	01/03/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077946	01/03/2017	

Labeler - H. J. Harkins Company Inc. (147681894)

Establishment

Name	Address	ID/FEI	Business Operations
H. J. Harkins Company Inc.		147681894	manufacture(52959-923) , relabel(52959-923) , repack(52959-923)

Revised: 12/2017 H. J. Harkins Company Inc.