CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet
Physicians Total Care, Inc.

Drug Facts

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

Do not use if you have ever had an allergic reactions 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.

Directions

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)

Inactive ingredients

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

Distributed by:

Physicians Total Care, Inc.

Tulsa, OK 74146

Principal Display Panel

NDC 0781-1684-64

Cetirizine HCl Tablets, USP

10 mg

antihistamine

30 Tablets.

Do not use if individual blister unit is open or torn

ALLERGY

Indoor & Outdoor Allergies

24 hour Relief of

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

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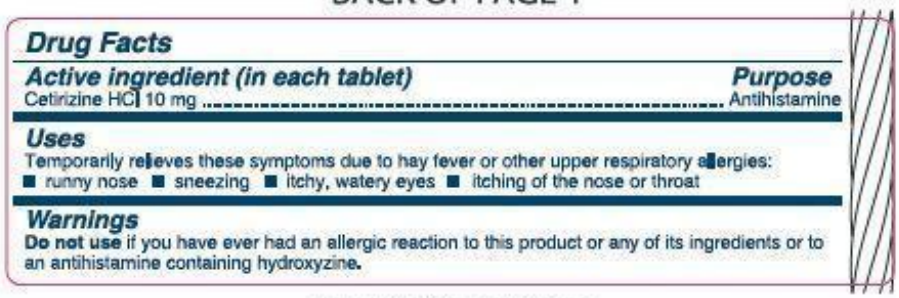

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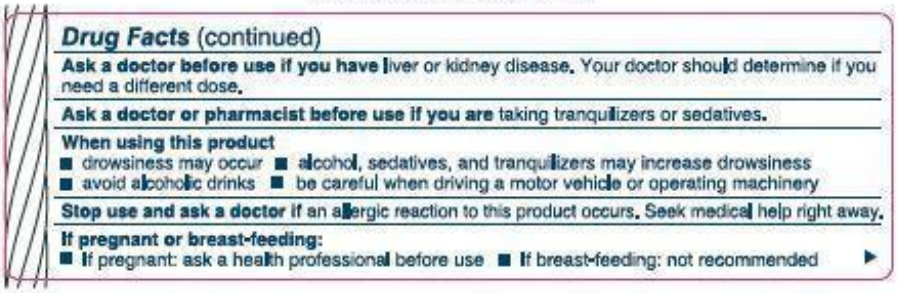

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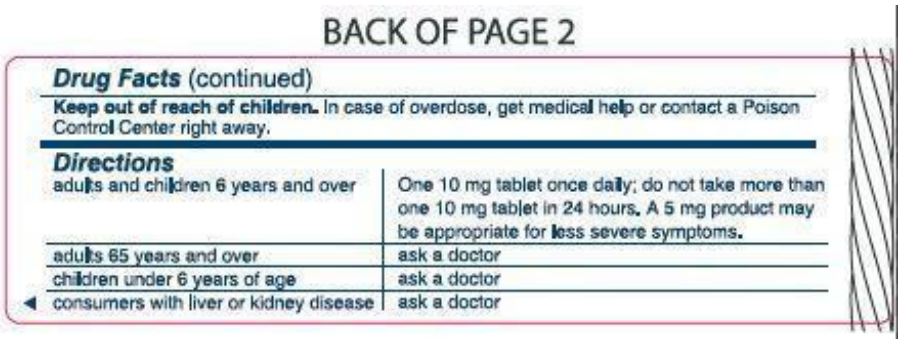

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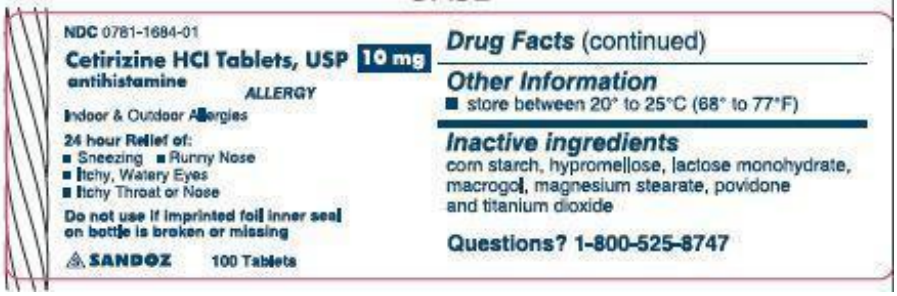
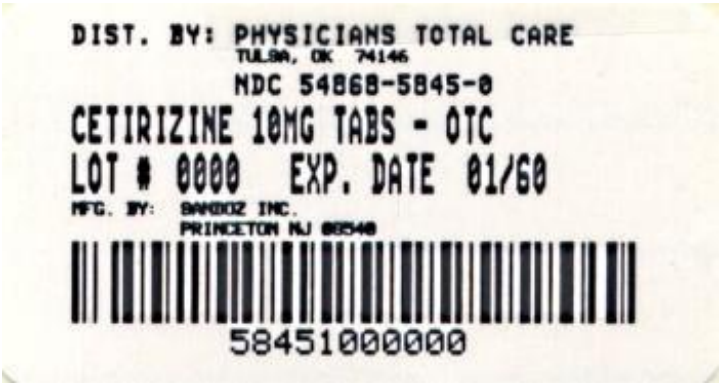


NDC 54868-5845-0

Cetirizine HCl Tablets, USP

10 mg

antihistamine



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54868-5845(NDC:0781-1684)
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**
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONES (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (round shape)	**Size**	8mm
Flavor		**Imprint Code**	SZ;906
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54868-5845-0	100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:54868-5845-1	14 in 1 BOTTLE; Type 0: Not a Combination Product		

3	NDC:54868-5845-2	30 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:54868-5845-3	90 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	ANDA077946	01/02/2008	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel(54868-5845)

Revised: 5/2015 Physicians Total Care, Inc.