CETIRIZINE HCL AND PSEUDOEPHEDRINE HCL ER- cetirizine hcl and pseudoephedrine hcl tablet, film coated, extended release
Physicians Total Care, Inc.

Drug Facts

Active Ingredient (in each extended release tablet)

Cetirizine HCl 5 mg

Pseudoephedrine HCl 120 mg

Purpose

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - itchy, watery eyes
  - nasal congestion
  - sneezing
  - itching of the nose or throat
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

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.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- thyroid disease
- diabetes
- glaucoma
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- 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

- **do not use more than directed**
- 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.
- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by fever

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

- do not break or chew tablet; swallow tablet whole

adults and children 12 years and over	take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.
adults 65 years and over	ask a doctor
children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other Information

- **Safety sealed: do not use if the imprinted bottle seal is open or torn (for bottle only).**
- **DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN (for blister package only).**

Store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature).

Inactive Ingredients

Colloidal silicon dioxide, croscarmellose sodium, D & C yellow aluminum lake, hypromellose, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate, povidone, and titanium dioxide.

Questions or comments?

1-800-525-8747

Sandoz Inc.

Princeton, NJ 08540

05-2010M

Relabeling of Additional Barcode by:
Physicians Total Care, Inc.
Tulsa, OK 74146

HOW SUPPLIED:

30 Tablets, Bottles	NDC 54868-5884-1
60 Tablets, Bottles	NDC 54868-5884-0
24 Tablets, Blister Pack	NDC 54868-5884-2

5 mg/120 mg Label

Cetirizine HCl and

Pseudoephedrine HCl

Extended Release Tablets

5 mg/120 mg

antihistamine/

nasal decongestant

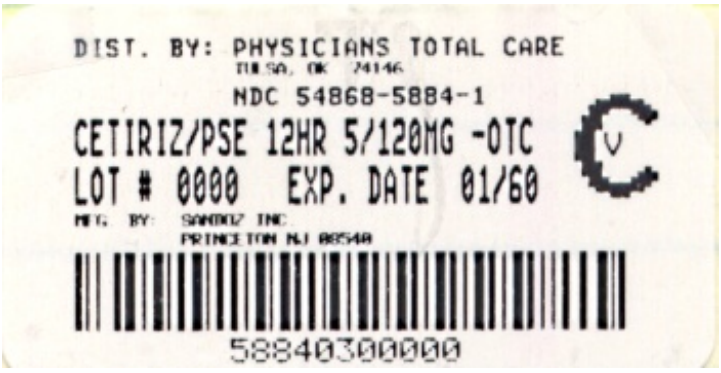
Indoor & Outdoor Allergies

ALLERGY & CONGESTION

12 hour Relief of

Runny Nose Itchy, Watery Eyes Sinus Pressure

Sneezing Itchy Throat or Nose Nasal Congestion



CETIRIZINE HCL AND PSEUDOEPHEDRINE HCL ER

cetirizine hcl and pseudoephedrine hcl tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54868-5884(NDC:0781-5285)
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2208 (15000 CPS) (UNII: Z78RG6M2N2)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	SZ912
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-5884-2	4 in 1 CARTON		
1		6 in 1 BLISTER PACK		
2	NDC:54868-5884-1	30 in 1 BOTTLE		
3	NDC:54868-5884-0	60 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077991	03/31/2008	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations

Physicians Total Care, Inc.		194123980	relabel

Revised: 6/2010 Physicians Total Care, Inc.