CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE - cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release
Chain Drug Marketing Association, Inc.

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, USP

Drug Facts

Active ingredients

Cetirizine HCl, USP 5 mg
Pseudoephedrine HCl, USP 120 mg

Purpose

Antihistamine
Nasal Decongestant

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
  - nasal congestion
- 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) (cer tain 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
- store between 20° to 25°C (68° to 77°F)
- do not use if inner safety seal is open or torn
- see side panel for batch number and expiration date

Inactive ingredients

hydroxyethyl cellulose, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, stearic acid, titanium dioxide

Imprinting Ink Contents: ammonium hydroxide, iron oxide black, isopropyl alcohol, N-butyl alcohol, propylene glycol, shellac glaze

Questions?

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

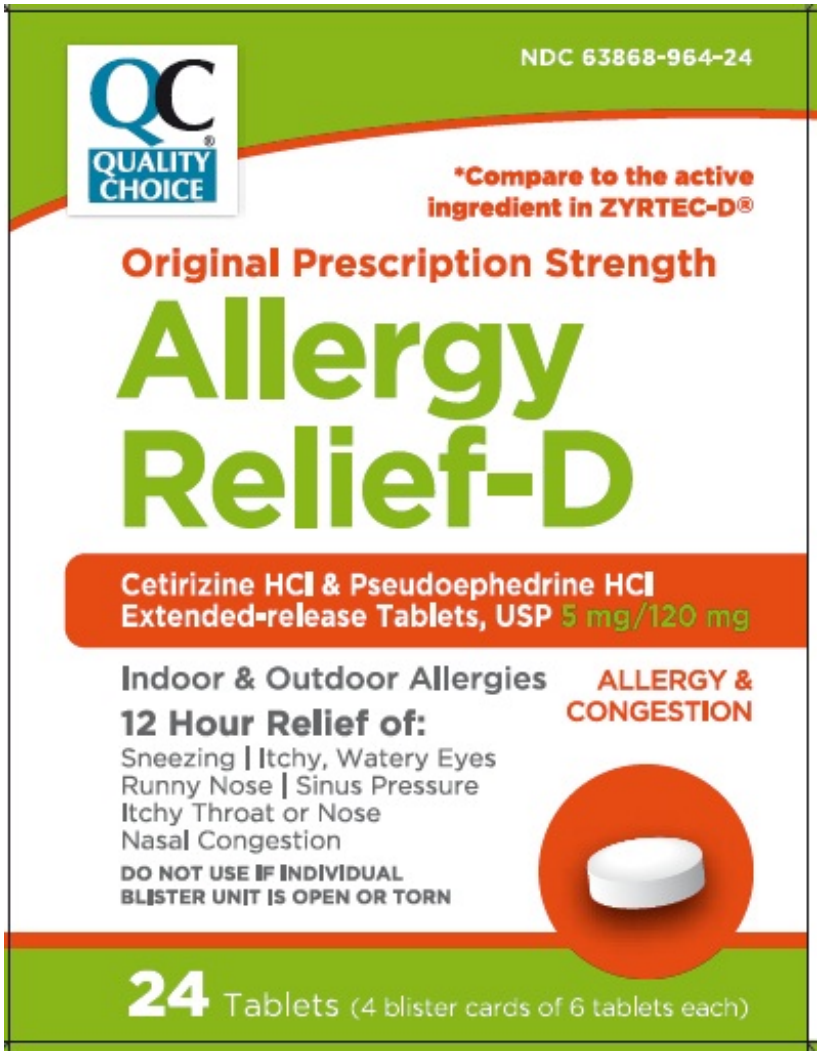
Principal Display Panel - Showbox

NDC 63868-964-24
***Compare to the active Ingredient in ZYRTEC-D®**
Original Prescription Strength
Allergy Relief-D
Cetirizine HCl and Pseudoephedrine HCl Extended-release Tablets, USP
5 mg/120 mg

Indoor & Outdoor Allergies

ALLERGY & CONGESTION
12 Hour Relief of:
Sneezing
Itchy, Watery Eyes
Runny Nose
Sinus Pressure
Itching Throat or nose
Nasal Congestion

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN
24 Tablets (4 blister cards of 6 tablets each)
QUALITY CHOICE



CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-964
Route of Administration	ORAL		

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**
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
AMMONIA (UNII: 5138Q19F1X)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
HYDROXYETHYL CELLULOSE (4000 MPA.S AT 1%) (UNII: ZYD53NBL45)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND (circular)	**Size**	9mm
Flavor		**Imprint Code**	915
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-964-24	4 in 1 CARTON	03/03/2016	
1	NDC:63868-964-73	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090922	03/03/2016	

Labeler - Chain Drug Marketing Association, Inc. (011920774)

Registrant - Sun Pharmaceutical Industries Limited (650172430)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(63868-964) , MANUFACTURE(63868-964)

Revised: 6/2016 Chain Drug Marketing Association, Inc.