CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE - cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release
Sun Pharmaceutical Industries, Inc.

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, USP

Active ingredients

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

Purposes

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 af ter 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 (1-800-222-1222).

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 carton is opened or if the blister unit is broken**
- 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 62756-915-62
Original Prescription Strength
Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-release Tablets, USP
5 mg/120 mg
Antihistamine/Nasal Decongestant
Indoor & Outdoor Allergies
ALLERGY & SINUS
SUN PHARMA
Actual Size
DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN
12 Tablets (2 blister cards of 6 tablets each)

Principal Display Panel - Blister pack

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablet, USP
5 mg/120 mg
Mfg. by: Sun Pharmaceutical Ind. Ltd. India.

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:62756-915
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 (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (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)	

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:62756-915-83	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/29/2012	
2	NDC:62756-915-63	1 in 1 CARTON	09/29/2012	
2	NDC:62756-915-60	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:62756-915-62	2 in 1 CARTON	09/29/2012	
3	NDC:62756-915-60	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:62756-915-73	4 in 1 CARTON	09/29/2012	
4	NDC:62756-915-60	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	09/29/2012	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(62756-915) , MANUFACTURE(62756-915)

Revised: 7/2022

Sun Pharmaceutical Industries, Inc.