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

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**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 lot 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

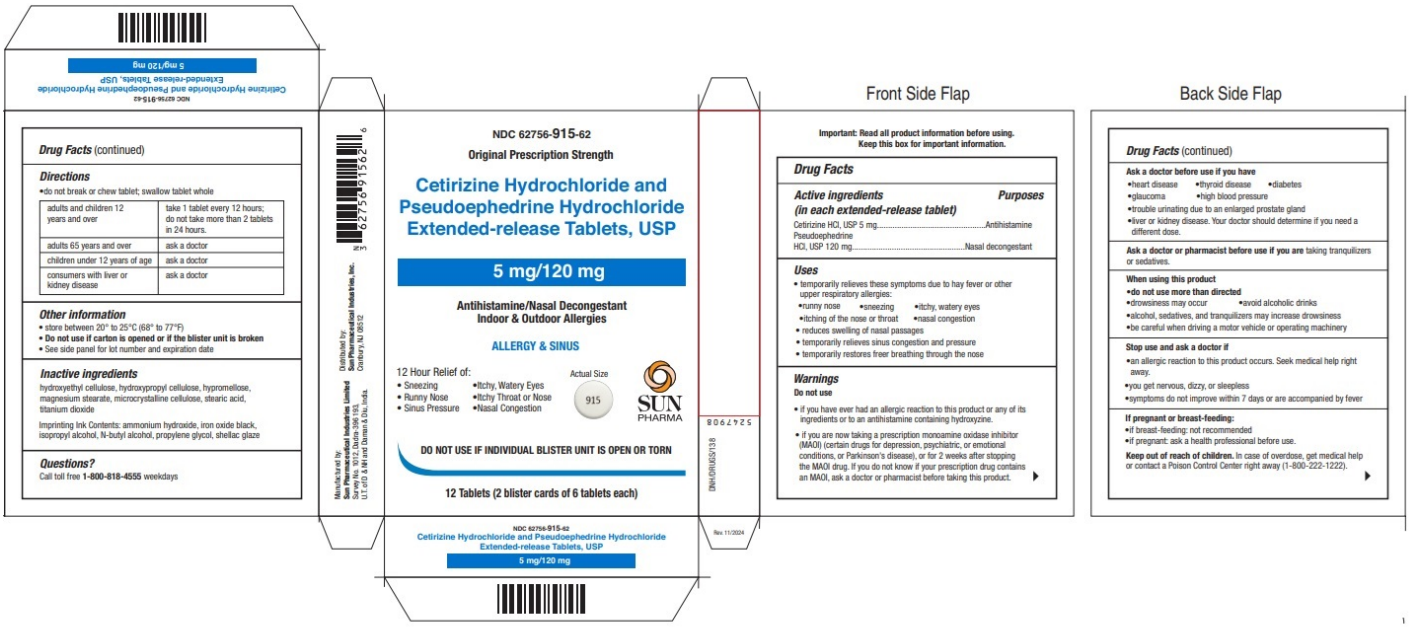
## Questions?

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) | |
| **HYDROXYETHYL CELLULOSE, UNSPECIFIED** (UNII: T4V6TWG28D) | |
| **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:62756-915-62 | 2 in 1 CARTON | 09/29/2012 | |
| **1** | NDC:62756-915-60 | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:62756-915-73 | 4 in 1 CARTON | 09/29/2012 | |
| **2** | 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: 11/2024

Sun Pharmaceutical Industries, Inc.