Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, USP

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) (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

<table>
<thead>
<tr>
<th>Adults and children 12 years and over</th>
<th>take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults 65 years and over</td>
<td>ask a doctor</td>
</tr>
<tr>
<td>Children under 12 years of age</td>
<td>ask a doctor</td>
</tr>
<tr>
<td>Consumers with liver or kidney disease</td>
<td>ask a doctor</td>
</tr>
</tbody>
</table>

Other information
- store between 20° to 25°C (68° to 77°F)
- do not use if inner safety seal is open or torn
- see top layer 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 & CONGESTION
SUN PHARMA
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

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td>NDC:62756-915</td>
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</table>

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ORAL</td>
<td></td>
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</table>

## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)</td>
<td>CETIRIZINE HYDROCHLORIDE</td>
<td>5 mg</td>
</tr>
<tr>
<td>PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DD9F)</td>
<td>PSEUDOEPHEDRINE HYDROCHLORIDE</td>
<td>120 mg</td>
</tr>
</tbody>
</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
</table>


HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)
HYPROMELLOSES (UNII: 3NXW29V3WO)
MAGNESIUM STEARATE (UNII: 70097M6I30)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
STEARIC ACID (UNII: 4ELV7Z65AP)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
AMMONIA (UNII: S138Q19F1X)
FERROSOFERRIC OXIDE (UNII: XM0M87F357)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHELLAC (UNII: 46N107B71O)

**Product Characteristics**

<table>
<thead>
<tr>
<th>Color</th>
<th>WHITE</th>
<th>Score</th>
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<tbody>
<tr>
<td>Shape</td>
<td>ROUND (circular)</td>
<td>Size</td>
<td>9mm</td>
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<tr>
<td>Flavor</td>
<td></td>
<td>Imprint Code</td>
<td>915</td>
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<tr>
<td>Contains</td>
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**Packaging**

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<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:62756-915-83</td>
<td>30 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>09/29/2012</td>
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<tr>
<td>2</td>
<td>NDC:62756-915-63</td>
<td>1 in 1 CARTON</td>
<td>09/29/2012</td>
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<tr>
<td>2</td>
<td></td>
<td>6 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
<td>09/29/2012</td>
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<td>3</td>
<td>NDC:62756-915-62</td>
<td>2 in 1 CARTON</td>
<td>09/29/2012</td>
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<tr>
<td>3</td>
<td></td>
<td>6 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
<td>09/29/2012</td>
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<tr>
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<td>4 in 1 CARTON</td>
<td>09/29/2012</td>
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<tr>
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<td>6 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
<td>09/29/2012</td>
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**Marketing Information**

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<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>ANDA</td>
<td>ANDA090922</td>
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**Labeler** - Sun Pharmaceutical Industries, Inc. (146974886)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
<tr>
<td>Sun Pharmaceutical Industries Limited</td>
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<td>650445203</td>
<td>ANALYSIS(62756-915), MANUFACTURE(62756-915)</td>
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Revised: 11/2018