ALLERGY RELIEF-D - cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release
Ohm Laboratories Inc.

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, USP

Drug Facts

Active ingredients (in each extended-release tablet)	***Purposes***
Cetirizine HCl, USP 5 mg	Antihistamine
Pseudoephedrine HCl, USP 120 mg	Nasal Decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of 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 at **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

Manufactured by:
Sun Pharmaceutical Industries Limited
Survey No. 1012, Dadra-396 193,
U.T. of D & NH and Daman & Diu, India.

Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

PRINCIPAL DISPLAY PANEL - 12 Tablet Blister Card Carton

†Compare To
the active ingredients of
Zyrtec-D®12Hr

NDC 51660-940-12

ohm®

12
Hour

Allergy Relief
Nasal Decongestant

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride
Extended-Release Tablets, USP 5 mg/120 mg
Antihistamine/Nasal Decongestant

12 Hour Relief of:
- Sneezing • Itchy, Watery Eyes • Sinus Pressure
- Runny Nose • Itchy Throat or Nose
- Nasal Congestion

Indoor & Outdoor Allergies
ALLERGY & SINUS

12 Tablets (2 blister cards of 6 tablets each)

Original Prescription Strength

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

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NON VARNISH
NO INK AREA

5247501

NDC 51660-940-12

Allergy Relief Nasal Decongestant

12 HOUR

ohm®

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†Compare To the active ingredients of Zyrtec-D® 12Hr

†Ohm is a registered trademark of Sun Pharmaceutical Industries, Inc.
All other trademarks are property of their respective owners.
DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN.

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R1223

3 51660 94012 1

2x6 Tablets

NO COATING

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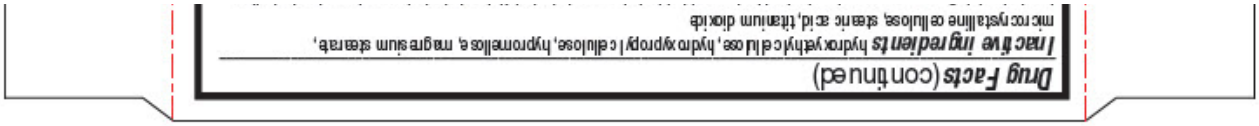

ALLERGY RELIEF-D

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

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-940
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)	
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:51660-940-12	2 in 1 CARTON	05/02/2017	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51660-940-24	4 in 1 CARTON	05/02/2017	
2		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	05/02/2017	

Labeler - Ohm Laboratories Inc. (184769029)

Registrant - Sun Pharmaceutical Industries Limited (650172430)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	MANUFACTURE(51660-940)

Revised: 12/2023 Ohm Laboratories Inc.