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

 $ohm^{\mathbb{R}}$

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

NO COATING

7501

52

	machinery
driving a motor vehicle or operating	be careful when
	as ani awonb

- exhirb cilorock boyer ur se shirb cilorock se drinkes = ses enoni yem aradi upne tibne, sevitebes, jorlock = =
 - don ctuse more than directed

When using this product tranquilizers or sedatives.

Ask a doctor or pharmacist before use if you are taking

- live ror kidney disease. Yourdcotor should de Érmina if you need a different dose. ■ trouble uninating due to an enlarged prostate gland
 - annssand boold rigin = essesib bionynt ■ assesib trean ■ Ask a doctor before use if you have

pharmacist be tore taking this product.

weeksafters topping the MMOI drug. If you do not know i your prescription drug contains an MMOI, sek a doctor or ore motion al conditions, or Parkin son's disease, or dollar es sbox o en inneonno montain se pre se più let von en su ovi i oritsino yzy, no isse en el en de un get no de pression, p.y.y. (IOAM) notibilini pydroxyzine.

gninistnoo eni metzirlitre ne ot noetneibergni și î to yn ș if you have ever had an allerg creaction to this product or esu ton od

sg ni maW

- temporarily restorestreer breathing through the rose temporarily relieves sinus corg estion and pressure
 - reduces swelling of resal passages

Drug Facts (continued)

NO COATING

2x6 Tablets

ne riching of rose or throat u oqsafiuco peseu 🛚 ∎itch ywatery eyes 🗦 Ses 🔳 tempo arily relieve sthese symptoms, due to hay fever or other upper respiratory allergies: tresta Decorgestant Pseu doephed rine HCI, USP 120 mg. Artifistamine Active ingredients (in each extended-release hablet) səsod.in.d

Drug Facts

NDC 51660-940-12

Zyrtec-D°12Hr

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

Original Prescription Strength

Manufactured by: Sun Pharmaceutical Industries Limited Survey No. 1012, Dadra-396 193, U.T. of D. & N.H and Daman & Diu, India. Distributed by: Ohm Laboratories Inc. New Brunswick, NJ 08901 Ohm is a registered trademark of Sun Pharmaceutical Indust All other trademarks are property of their respective owners. DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN Industries, ਰ

R1223

12 Tablets (2 blister cards of 6 tablets each)

Questions? call toll free 1-800-818-4555 weekdays

Imprinting Ink Contents: ammonium by doxide, inon oxide black, isopropyl alcohol, N-butyl alcohol, propylere glycol, shellas

Hou

†Compare To the active ingredients of

Indoor & Outdoor Allergies

ALLERGY & SINUS

 sæ side panel for batch number and expiration date donotuse if carb nis opened or if the blister unit is broke

ask a doc br

SEK SIGOCOL

SEK STOCEDI

enuck hours.

donot break or chew tablet; swallow tablet whole

Keep out of reach of children. In case of overdose, get it breas tfeeding: not recommended if pregnant ask a health professional before use

en syeb Tninhiw e von qmi bon ob amontqm ya ■

■ an allengic resection to this productocours. Seek medical help right away.

de not take more than 2 table ts

take 1 tablet every 12 hours,

or contacta Poison Control Center right awayat

■ sbre between 20° to 25°C (68° to 77°F)

no ther informa to on

consumers with liver or kidney disease

adults 65 years and over

12 years of age

children under

12 years and over

adults and children

medical help or co

Unibeeltæeid o heageigh

Stop us e and ask a doctorif

■ you get nervous, dizzy, or sleepless

Drug Facts (continued)

accompanied by fever

D irectio ns

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: 640047KTOA) (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: 46N107B710)	
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.