# ALLERGY RELIEF-D- cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release RITE AID

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# **Allergy relief-D**

# **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

**DISTRIBUTED BY:** RITE AID,

200 NEWBERRY COMMONS, ETTERS, PA 17319

# PRINCIPAL DISPLAY PANEL - 12 Tablet Blister Card Carton

NDC 11822-9994-1 12 HOUR

Compare to the active ingredient of Zyrtec-D<sup>®</sup> 12hr\*

ORIGINAL PRESCRIPTION STRENGTH

ALLERGY RELIEF
NASAL DECONGESTANT

CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, USP 5 mg/120 mg

ANTIHISTAMINE/NASAL DECONGESTANT

INDOOR & OUTDOOR ALLERGIES ALLERGY & SINUS

12 HOUR RELIEF OF Sneezing • Runny nose • Nasal congestion Itchy, watery eyes • Sinus pressure Itchy throat or nose

ACTUAL SIZE

12 TABLETS

(2 blister cards of 6 tablets each)

 be careful when driving a motor vehicle or operating alcohol, sedatives, and tranquilizers may increase quowajueza iusò occni.
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Drug Facts (continued)

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Drug Facts

12 HOUR

NDC 11822-9994-1

Compare to the active ingredient of Zyrtec-D® 12hr\*

ORIGINAL PRESCRIPTION STRENGTH

CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, USP 5 mg/120 mg

### ANTIHISTAMINE/NASAL DECONGESTANT

**INDOOR & OUTDOOR ALLERGIES ALLERGY & SINUS** 

12 HOUR RELIEF OF

Sneezing · Runny nose · Nasal congestion Itchy, watery eyes · Sinus pressure Itchy throat or nose

Non Varnish Area

**Batch No** 

**TABLETS** 

(2 blister cards of 6 tablets each)

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

Imprinting Ink Contents: ammonium hydroxide, iron oxide black, isopropyl alcohol, N-butyl alcohol, propylene glycol, shellac microcrystalline cellulose, stearic acid, titanium dioxide Inactive ingredients hydroxyethy celulose, hydroxypropyl celulose, hypromellose, magnesium stearate,

nund racts (continued)

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN DISTRIBUTED BY: RITE AID, 200 NEWBERRY COMMONS, ETTERS,

'All trademark are properly of their respective owners. This product is no affiliated with the makers/owners of Zyrtec-D.

NDC:11822-9994

# **ALLERGY RELIEF-D**

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

Product Information			
	Product Type	HUMAN OTC DRUG	Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	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			

F	Packaging			
#	t Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:11822- 9994-1	2 in 1 CARTON	07/20/2023	

1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822- 9994-2	6 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/20/2023	

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
ANDA	ANDA090922	07/20/2023		

# **Labeler -** RITE AID (014578892)

# **Registrant -** Sun Pharmaceutical Industries Limited (650172430)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Sun Pharmaceutical Industries Limited		650445203	MANUFACTURE(11822-9994)	

Revised: 8/2023 RITE AID