ALLERGY RELIEF-D - cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release
EQUATE (WAL-MART STORES, INC.)

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, USP

Drug Facts

Active ingredients (in each extended-release tablet)	***Purpose***
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) (cer tain 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?

1-888-287-1915

DISTRIBUTED BY: Walmart Inc.,
Bentonville, AR 72716

PRINCIPAL DISPLAY PANEL - 24 Tablet Blister Pack Carton

NDC 49035-982-24

equate™

Compare to
Zyrtec-D® 12Hr
active ingredients*

Allergy Relief
Nasal Decongestant

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

INDOOR AND OUTDOOR ALLERGIES

12
HOURS

ALLERGY & CONGESTION

12 Hour Relief of:

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

Original prescription strength

Actual Size

24
TABLETS
(4 blister cards of
6 tablets each)

Non Varnish Area

Batch No.

Expiration Date:

Drug Facts (continued)

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

Questions? 1-888-287-1915

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN.

Original prescription strength

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

Actual Size

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12 HOURS

ALLERGY & CONGESTION

12 Hour Relief of:

INDOOR AND OUTDOOR ALLERGIES

Allergy Relief Nasal Decongestant

Cetirizine Hydrochloride and **Pseudoephedrine** Hydrochloride Extended-release Tablets, USP 5 mg/120 mg

Antihistamine/Nasal Decongestant

Compare to Zyrtec-D® 12Hr active ingredients*

equate™

NDC 49035-982-24

602483

6 81131 08926 5

Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call 1-888-287-1915.

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Zyrtec-D® 12 Hour. 0519

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519628

519628

ALLERGY RELIEF-D

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49035-982
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:49035-982-24	4 in 1 CARTON	05/31/2019	
1		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	05/31/2019	

Labeler - EQUATE (WAL-MART STORES, INC.) (051957769)

Registrant - Sun Pharmaceutical Industries Limited (650172430)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(49035-982) , MANUFACTURE(49035-982)

Revised: 5/2019 EQUATE (WAL-MART STORES, INC.)