

**FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCL- fexofenadine hcl and pseudoephedrine hcl tablet, extended release
CVS Pharmacy, Inc**

Fexofenadine HCl 180 mg and Pseudoephedrine HCl 240 mg ER Tablets, USP

Active ingredient(s)

Fexofenadine HCl USP, 180 mg

Pseudoephedrine HCl USP, 240 mg

Purpose

Antihistamine

Nasal decongestant

Use(s)

- 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
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- 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
- 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.
- if you have difficulty swallowing

Ask a doctor before use if you have

- heart disease
- thyroid disease
- glaucoma
- high blood pressure

- diabetes
- trouble urinating due to an enlarged prostate gland
- kidney disease. Your doctor should determine if you need a different dose.

When using this product

- **do not take more than directed**
- do not take at the same time as aluminum or magnesium antacids
- do not take with fruit juices (see Directions)
- the tablet coating may be seen in the stool (this is normal). Continue to take as directed (see Directions).

Stop use and ask doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve within 7 days or are accompanied by a fever
- you get nervous, dizzy, or sleepless

If pregnant or breast-feeding,

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 divide, crush, chew or dissolve the tablet; swallow tablet whole

adults and children 12 years of age and over	take 1 tablet with a glass of water every 24 hours on an empty stomach; do not take more than 1 tablet in 24 hours
children under 12 years of age	do not use
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

Other information

- each tablet contains: **28 mg sodium**
- safety sealed: do not use if carton is opened or if individual blister units are torn or opened
- store between 20° - 25°C (68° - 77°F)
- FDA approved dissolution test specifications differ from USP

Inactive ingredients

acetone, black iron oxide, cellulose acetate, colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1 aluminum lake, hypromellose, isopropyl alcohol,

magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, propylene glycol, red iron oxide, sodium chloride, talc, titanium dioxide, water

Questions?

Questions? Call 1-888-375-3784 Weekdays (9am - 8pm EST)

Distributed by:

Dr. Reddy's Laboratories, Inc.

Princeton, NJ 08540

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	240 mg

Inactive Ingredients

Ingredient Name	Strength
ACETONE (UNII: 1364PS73AF)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
COPOVIDONE (UNII: D9C330MD8B)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POVIDONE K30 (UNII: U725QWY32X)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	892
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-018-10	2 in 1 CARTON	11/30/2022	
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51316-018-15	3 in 1 CARTON	11/30/2022	
		5 in 1 BLISTER PACK; Type 0: Not a Combination		

2

5 in 1 BLISTER PACK; Type O: Not a Combination Product

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079043	11/30/2022	

Labeler - CVS Pharmacy, Inc (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Dr.Reddy's Laboratories Limited (FTO III)		918608162	analysis(51316-018) , manufacture(51316-018)

Revised: 1/2024

CVS Pharmacy, Inc