

FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCl- fexofenadine hcl and pseudoephedrine hci tablet, extended release
CVS Pharmacy

Fexofenadine HCl 60 mg and Pseudoephedrine HCl 120 mg ER Tablets USP

Active ingredient(s)

Fexofenadine HCl USP, 60 mg

Pseudoephedrine HCl USP, 120 mg

Purpose

Antihistamine

Nasal decongestant

Use(s)

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

Pregnancy/Breastfeeding

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 12 hours on an empty stomach; do not take more than 2 tablets 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

- safety sealed: do not use if carton is opened or if individual blister units are torn or opened
- this product meets the requirements of USP dissolution test 3.

Storage

- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

corn starch, croscarmellose sodium, colloidal silicon dioxide, ferric oxide, hypromellose, kollidon SR, magnesium stearate, mannitol, powder cellulose, and triethyl citrate.

Questions or comments?

call toll-free **1-888-375-3784**

Manufactured by:

Dr. Reddy's Laboratories Limited

Bachupally - 500 090 INDIA

Carton label

#197233
FPD 100%
UP C # 050 428 29 0538
X XXXXXX XXXXXX X

CVS Health.

Original Prescription Strength
ALLERGY & CONGESTION RELIEF
Allergy Relief D
FEXOFENADINE HCl 60 mg/Anthistamine
PSEUDOEPHEDRINE HCl 120 mg/Nasal decongestant
EXTENDED RELEASE TABLETS, USP

INDOOR/OUTDOOR RELIEF OF:

- Nasal & sinus congestion due to colds or allergies
- Sneezing; Runny nose; Itchy, watery eyes & itchy nose or throat due to allergies

Non-drowsy

30 EXTENDED-RELEASE TABLETS

CVS Health.

Original Prescription Strength
ALLERGY & CONGESTION RELIEF
Allergy Relief D
FEXOFENADINE HCl 60 mg/Anthistamine
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Non-drowsy

No Coating
150076550
FPD

No Coating
Area

No Coating
Area

No Coating
Area

Compare to the active ingredients in Allegra-D®
12 Hour Allergy & Congestion Tablets*

*This product is not manufactured or distributed by Chatten, Inc. (part of the Sanofi Group), distributor of Allegra-D® 12 Hour Allergy & Congestion Tablets. Allegra-D® is a registered trademark of Aventisub LLC.

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CVS Quality
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No Coating
Area

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Area

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Area

No Coating
Area

FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCl		
fexofenadine hcl and pseudoephedrine hci tablet, extended release		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:69842-249(NDC:55111-447)
Route of Administration	ORAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg
Inactive Ingredients		
Ingredient Name	Strength	
MANNITOL (UNII: 3OWL53L36A)		
POWDERED CELLULOSE (UNII: SMD1X3XO9M)		
STARCH, CORN (UNII: O8232NY3SJ)		
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		

HYPROMELLOSES (UNII: 3NXW29V3WO)

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics

Color	WHITE (off white to pale yellow one layer and light red to red other layer)	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	R;195
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-249-20	4 in 1 CARTON	07/19/2019	
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69842-249-30	6 in 1 CARTON	07/19/2019	
2		5 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	ANDA076667	07/19/2019	

Labeler - CVS Pharmacy (062312574)

Revised: 7/2019

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