

ALLERGY AND CONGESTION- fexofenadine hcl and pseudoephedrine hcl tablet, extended release
Strategic Sourcing Services, LLC

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
- 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 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
- store between 20° to 25°C (68° to 77°F) store between 20° to 25°C (68° to 77°F)
- this product meets the requirements of USP dissolution test 3.

Inactive ingredients

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

Questions?

Call 1-888-375-3784

Distributed by:

Dr. Reddy's Laboratories, Inc.

Princeton, NJ 08540

Made in India

Principal Display Panel



Blister carton

ALLERGY AND CONGESTION			
fexofenadine hcl and pseudoephedrine hci tablet, extended release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62011-0455
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE -		FEXOFENADINE	60 mg

UNII:E6582LOH6V)		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)				
CROSCARMELLOSE 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 (buff white to pale yellow color and other layer light red to red color)		Scoreno score	
Shape	CAPSULE		Sizesize16mm	
Flavor			Imprint CodeR;195	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62011-0455-1	4 in 1 CARTON	07/27/2020	
1		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	07/27/2020	

Labeler - Strategic Sourcing Services, LLC (116956644)

Revised: 2/2021

Strategic Sourcing Services, LLC