FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCI- fexofenadine hcl and pseudoephedrine hci tablet, extended release
Dr. Reddy's Laboratories Limited

Fexofenadine HCl 60 mg and Pseudoephedrine HCI 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 takeas 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 contacta 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

Principal Display Panel

Blister carton 20's (4x5 unit-dose)

FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCI

fexofenadine hcl and pseudoephedrine hci tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55111-447
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXOFENADINE HYDROCHLORIDE (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)	
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 (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:55111-447-35	2 in 1 CARTON		
1	NDC:55111-447-07	5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:55111-447-14	4 in 1 CARTON		
2	NDC:55111-447-07	5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:55111-447-31	6 in 1 CARTON		
3	NDC:55111-447-07	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	11/18/2014	

Labeler - Dr. Reddy's Laboratories Limited (650562841)

Revised: 11/2013 Dr. Reddy's Laboratories Limited