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

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

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

- 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)
- this product meets the requirements of USP Dissolution Test 4

Inactive ingredients

acetyltributyl citrate, colloidal silicon dioxide, copovidone, croscarmellose sodium, ethylcellulose, hydrogenated vegetable oil, hypromellose, microcrystalline cellulose, polyethylene glycol, sodium stearyl fumarate, talc and titanium dioxide.

Questions?

Call **1-888-375-3784**

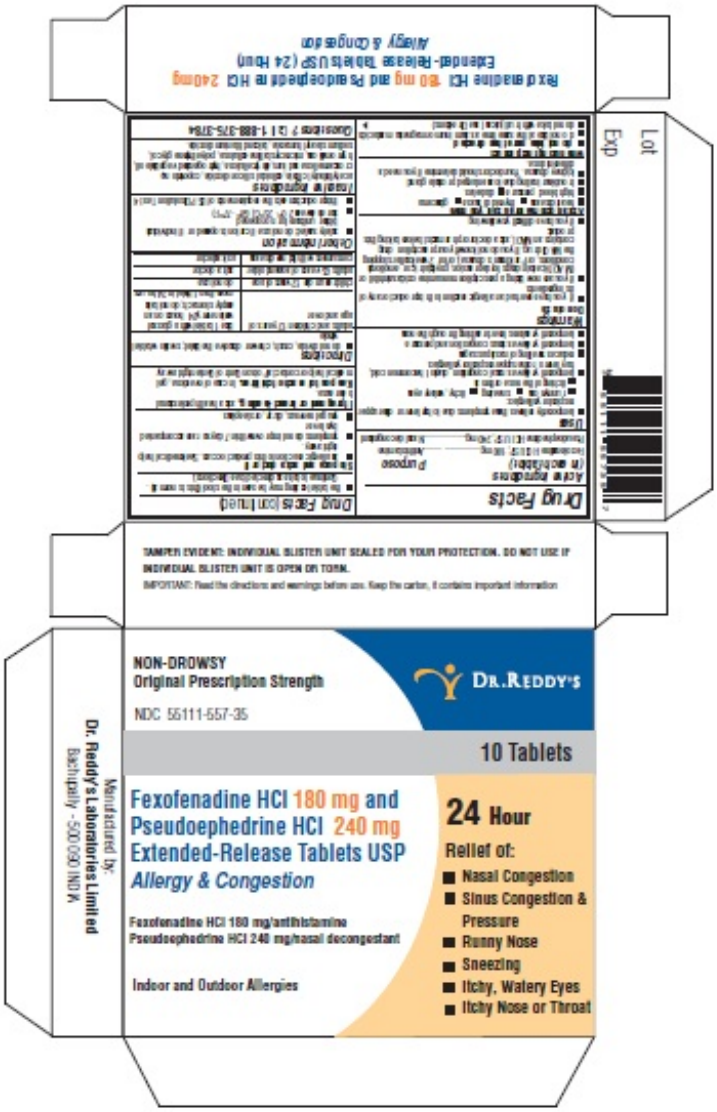
Manufactured by:

Dr. Reddy’s Laboratories Limited

Bachupally - 500 090 INDIA.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL SECTION

Blister carton label : 10's



FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCI

fexofenadine hcl and pseudoephedrine hci tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55111-557
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**

ACETYLTRIBUTYL CITRATE (UNII: 0ZBX0N59RZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
COPOVIDONE (UNII: D9C330MD8B)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	RDY;572
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-557-07	1 in 1 CARTON	08/24/2011	
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:55111-557-35	2 in 1 CARTON	08/24/2011	
2		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:55111-557-29	3 in 1 CARTON	08/24/2011	
3		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	ANDA079043	08/24/2011	

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

Establishment

Name	Address	ID/FEI	Business Operations
Dr.Reddy's Laboratories Limted (FTO III)		918608162	analysis(55111-557) , manufacture(55111-557)

Revised: 12/2018 Dr.Reddy's Laboratories Limited