

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

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**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 hcl tablet, extended release			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62011-0455
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE -	FEXOFENADINE	60 mg	

UNII:E6582LOH6V)	HYDROCHLORIDE	60 mg		
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg		
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
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)				
<b>Product Characteristics</b>				
<b>Color</b>	WHITE (buff white to pale yellow color and other layer light red to red color)	<b>Score</b>	no score	
<b>Shape</b>	CAPSULE	<b>Size</b>	16mm	
<b>Flavor</b>		<b>Imprint Code</b>	R;195	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:62011-0455-1	4 in 1 CARTON	07/27/2020	07/31/2024
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA076667	07/27/2020		

**Labeler** - Strategic Sourcing Services, LLC (116956644)

Revised: 10/2024

Strategic Sourcing Services, LLC