

**FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCl- fexofenadine hcl and pseudoephedrine hci tablet, extended release**  
**Safeway Inc**

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**Fexofenadine HCl and Pseudoephedrine HCl ER Tablets USP 180240 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
- 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**

- 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 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

**Storage**

store between 20° - 25°C (68° - 77°F)

**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 or comments?**

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

Manufactured by:

**Dr. Reddy's Laboratories Limited**

Bachepalli - 502 325 INDIA.

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL SECTION**



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

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	RDY;572
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-557-35	2 in 1 CARTON		
1		5 in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079043	02/05/2013	

**Labeler** - Safeway Inc (009137209)

Revised: 2/2014

Safeway Inc