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

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## Fexofenadine HCl and Pseudoephedrine HCI 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 contacta Poison Control Center right away.

#### Directions

• do not divide, crush, chew or dissolve the tablet; swallow tablet whole

	take 1 tablet with a glass of water every 24 hours on an empty stomach; do
of age and over	not take more than 1 tablet in 24 hours
children under 12 years of	do not use
age	
Adults 65 years of age and	ask a doctor
older	
consumers with kidney	ask a doctor
disease	

#### 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

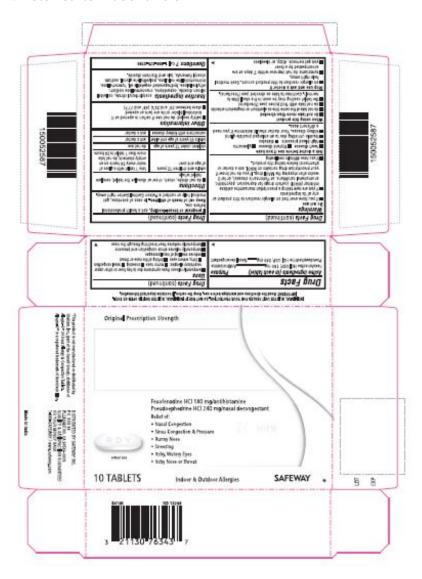
Manufactured by:

#### Dr. Reddy's Laboratories Limited

Bachepalli - 502 325 INDIA.

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL SECTION

## 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:21130-557(NDC:55111-557)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>FEXO FENADINE HYDRO CHLO RIDE</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII: E6582LOH6 V)	FEXOFENADINE HYDROCHLORIDE	180 mg	
PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	240 mg	

Inactive Ingredients		
	Ingredient Name	Strength

ACETYLTRIBUTYL CITRATE (UNII: 0ZBX0N59RZ)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
COPOVIDONE (UNII: D9 C330 MD8 B)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
COLLOIDAL SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	

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

P	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