

ALLERGY AND CONGESTION- fexofenadine hcl and pseudoephedrine hci tablet, extended release

Rite Aid Corporation

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

[illegible]

fexofenadine hcl and pseudoephedrine hci tablet, extended release

| Product Information | | | | |
|---|--|--|-------------------------------|--------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11822-7388(NDC:43598-823) | |
| Route of Administration | ORAL | | | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V) | | FEXOFENADINE HYDROCHLORIDE | 60 mg | |
| PSEUDOEPHEDRINE HYDRO CHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | | PSEUDOEPHEDRINE HYDROCHLORIDE | 120 mg | |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| MANNITOL (UNII: 3OWL53L36A) | | | | |
| PO WDERED CELLULOSE (UNII: SMD1X3XO9M) | | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | | | | |
| SILICON DIO XIDE (UNII: ETJ7Z6XBU4) | | | | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | | | | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | WHITE (buff white to pale yellow color and other layer light red to red color) | Score | no score | |
| Shape | CAPSULE | Size | 16mm | |
| Flavor | | Imprint Code | R;195 | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:11822-7388-5 | 4 in 1 CARTON | 07/19/2019 | |
| 1 | | 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 | | 07/19/2019 | |

Labeler - Rite Aid Corporation (014578892)