

**FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCL- fexofenadine hcl and pseudoephedrine hcl tablet, extended release  
RUGBY LABORATORIES**

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**Fexofenadine HCl 180 mg and Pseudoephedrine HCl 240 mg ER Tablets, USP**

**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**

- each tablet contains: **28 mg sodium**
- 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)
- FDA approved dissolution test specifications differ from USP

**Inactive ingredients**

acetone, black iron oxide, cellulose acetate, colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1 aluminum lake, hypromellose, isopropyl alcohol,

magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, propylene glycol, red iron oxide, sodium chloride, talc, titanium dioxide, water

**Questions?**

**Questions?** Call 1-888-375-3784 Weekdays (9am - 8pm EST)

Distributed by:

RUGBY LABORATORIES.

Indianapolis, IN 46268

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**Drug Facts (continued)**

**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
- kidney disease
- high blood pressure
- 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
- the tablet coating may be seen in the stool (this is normal).
- Continue to take as directed (see Directions).

**Stop use and ask a 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

**Questions or comments?**  
Call 1-888-375-3784 Weekdays (9am - 8pm EST)

**Inactive Ingredients**  
acetate, colloidal silicon dioxide, copovidone, croscarmellose sodium, FD & Blue #1 aluminum lake, hypromellose, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxane, polyurethane glycol, titanium dioxide, water

**Other Information**

- each tablet contains sodium 28 mg
- safety sealed: do not use if carton is opened or if individual blister units are torn or opened
- store between 20° and 25°C (68° and 77° F)
- FDA approved dissolution test specifications differ from USP

**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
- ask a doctor if you have kidney disease
- ask a doctor if you are pregnant or breastfeeding

**Drug Facts (continued)**

**Drug Facts (continued)**

**Active Ingredients (in each tablet)**

- Fexofenadine HCl USP, 180 mg
- Pseudoephedrine HCl USP, 240 mg

**Purpose**  
Antihistamine  
Nasal decongestant

**Uses**

- 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

**Drug Facts (continued)**

**IMPORTANT: Read the directions and warnings before use. Keep the carton, it contains important information.**

**TAMPER EVIDENT: INDIVIDUAL BLISTER UNIT SEALED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN.**

\*All Trade names are the property of the respective owners

**Rugby®**

**Non-Drowsy**

**Fexofenadine HCl 180 mg and Pseudoephedrine HCl 240 mg Extended-Release Tablets, USP**

**180 mg/240 mg**

**Antihistamine and Nasal Decongestant Allergy & Congestion**

**24 Hour**

**Indoor / Outdoor Relief of:**

- Nasal and Sinus Congestion Due to Colds or Allergies
- Sneezing; Runny Nose; Itchy, Watery Eyes and Itchy Nose or Throat Due to Allergies

**15 Extended-Release Tablets**

**Actual Size**



**NDC 0536-1394-26**

Compare to the active ingredients in Allegra-D® 24 Hour Allergy and Congestion Tablets\*

Rev. 05/23 R-HS Re-order No. 371160

**Distributed by:**  
**RUGBY LABORATORIES**  
Indianapolis, IN 46268  
Questions or comments?  
Call (800) 616-2471  
www.rugbypharmaceutical.com

**LOT/EXP**

**No Coating Lot / Exp:**

0536139426 4

**Rugby®**

**Fexofenadine HCl 180 mg and Pseudoephedrine HCl 240 mg Extended-Release Tablets, USP**

**180 mg/240 mg**

**NDC 0536-1394-26**

<b>FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCL</b>			
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:0536-1394
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FEXOFENADINE HYDROCHLORIDE</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	240 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>ACETONE</b> (UNII: 1364PS73AF)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CELLULOSE ACETATE</b> (UNII: 3J2P07GVB6)	
<b>COPOVIDONE</b> (UNII: D9C330MD8B)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>Polyethylene Glycol, Unspecified</b> (UNII: 3WJQ0SDW1A)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	892
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1394-26	3 in 1 CARTON	10/06/2023	
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	ANDA079043	11/30/2022	

**Labeler** - RUGBY LABORATORIES (079246066)

### Establishment

Name	Address	ID/FEI	Business Operations
Dr.Reddy's Laboratories Limited (FTO III)		918608162	analysis(0536-1394) , manufacture(0536-1394)

Revised: 1/2024

RUGBY LABORATORIES