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

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

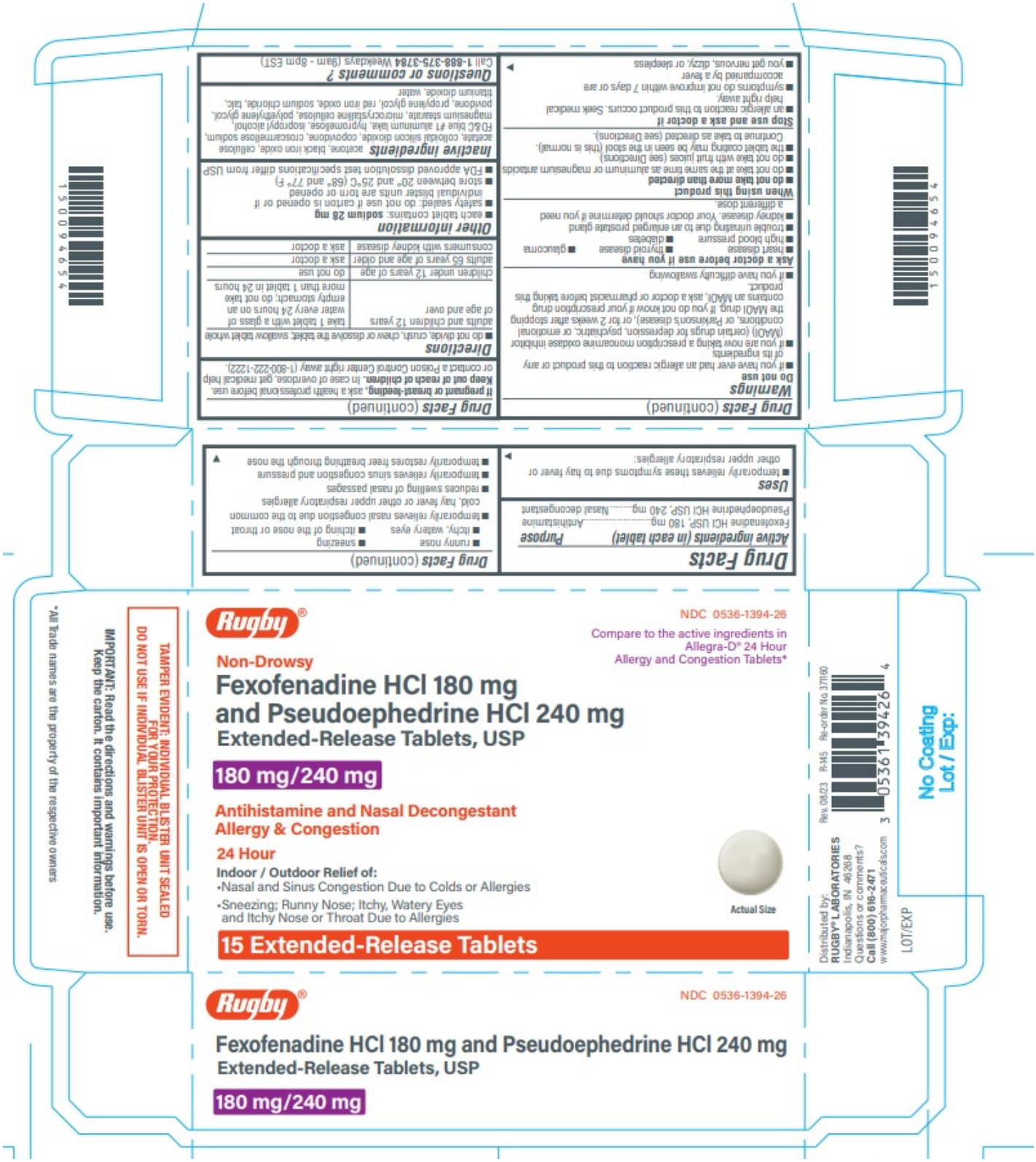
Questions?

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

Distributed by:

RUGBY LABORATORIES.

Indianapolis, IN 46268



FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCL

fexofenadine hcl and pseudoephedrine hcl tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1394
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ACETONE (UNII: 1364PS73AF)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
COPOVIDONE (UNII: D9C330MD8B)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
Polyethylene Glycol, Unspecified (UNII: 3WQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POVIDONE K30 (UNII: U725QWY32X)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	892
Contains			

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