FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE- fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, extended release
RUGBY LABORATORIES

Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 60 mg/120 mg

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 relives 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)
- FDA approved dissolution test specifications differ from USP.
- FDA approved organic impurities test procedure differs from USP Procedure 1.

Inactive ingredients

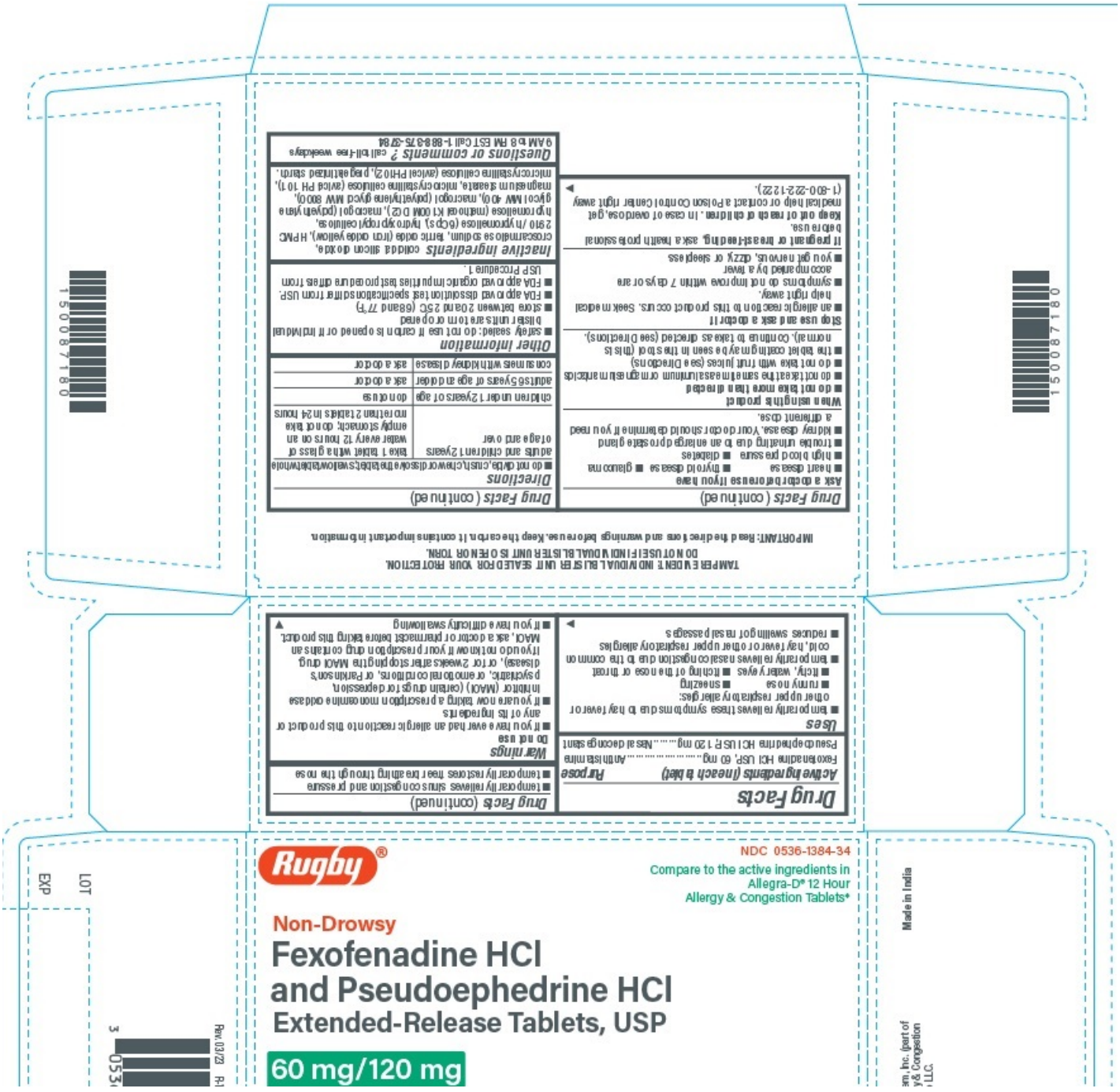
colloidal silicon dioxide, croscarmellose sodium, ferric oxide (iron oxide yellow), HPMC 2910 / hypromellose (6 Cps), hydroxypropyl cellulose, hypromellose (methocel K100M DC2), macrogol (polyethylene glycol MW 400), macrogol (polyethylene glycol MW 8000), magnesium stearate, microcrystalline cellulose (avicel PH 101), microcrystalline cellulose (avicel PH102), pregelatinized starch.

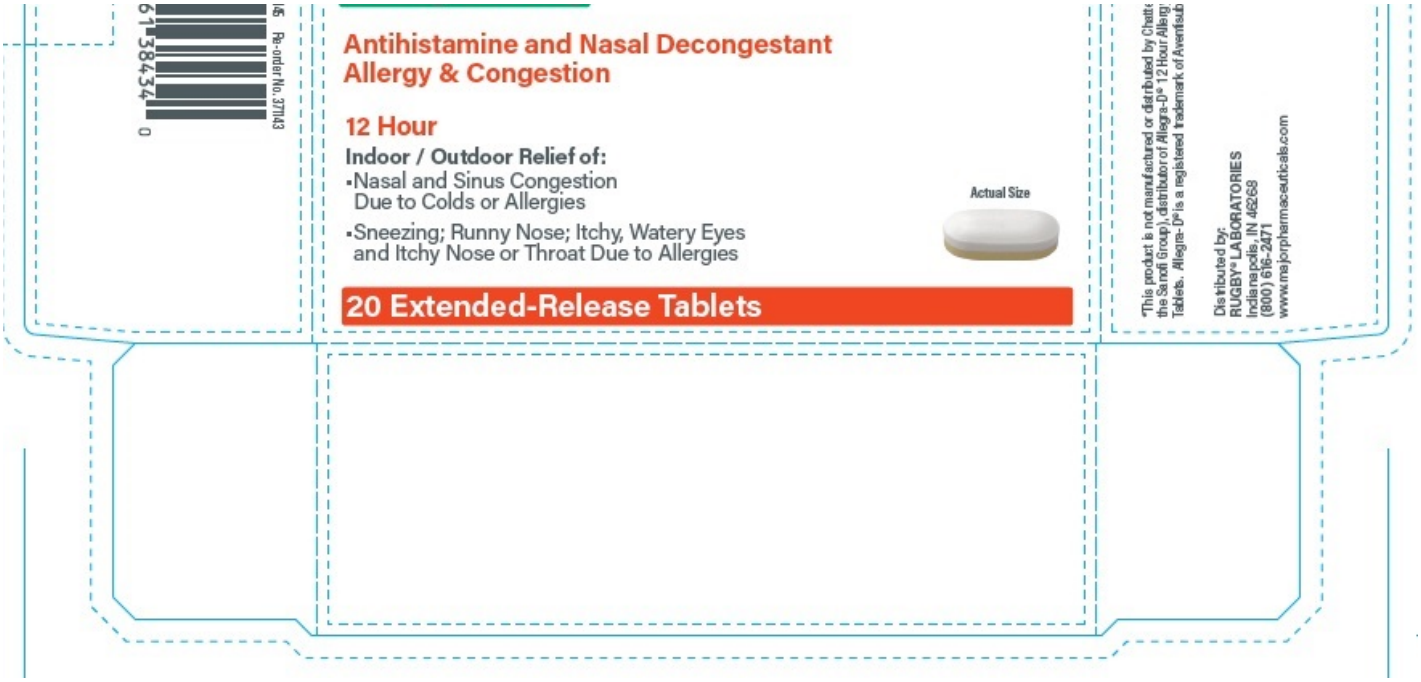
Questions?

Call toll-free weekdays 9 AM to 8 PM EST Call **1-888-375-3784**

Principal Display Panel

Blister Carton:





FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1384
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Magnesium Stearate (UNII: 70097M6I30)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Hypromellose 2208 (100000 Mpa.S) (UNII: VM7F0B23ZI)	
HYDROXYPROPYL CELLULOSE (45000 WAMW) (UNII: 8VAB711C5E)	
Hypromellose 2910 (6 Mpa.S) (UNII: 0WZ8WG20P6)	
Polyethylene Glycol 8000 (UNII: Q662QK8M3B)	
Starch, Corn (UNII: O8232NY3SJ)	

MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	

Product Characteristics

Color	WHITE (one white to off-white color layer and other light yellow to yellow color)	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1384-07	6 in 1 CARTON	05/19/2023	
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-1384-34	4 in 1 CARTON	05/19/2023	
2		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	ANDA215434	03/31/2022	

Labeler - RUGBY LABORATORIES (079246066)

Revised: 5/2023 RUGBY LABORATORIES