FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE - fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release
Aurohealth LLC

Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets USP

Drug Facts

Active ingredients (in each tablet)

Fexofenadine HCl USP 60 mg
Pseudoephedrine HCl USP 120 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

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 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

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 (1-800-222-1222) 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 at 20-25°C (68-77°F).
- Meets USP dissolution test 7

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, ferric oxide yellow, hydroxypropyl cellulose, hypromellose, lactose monohydrate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch (maize), stearic acid

Questions or Comments?

call 1-855-274-4122

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

Manufactured for:
AUROHEALTH LLC
2572 Brunswick Pike
Lawrenceville, NJ 08648

Made in India
Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1 x 10 Blister Carton

AUROHEALTH

NDC 58602-807-83

*Compare to the active ingredients
in Allegra-D® 12 Hour
Allergy & Congestion Tablets

Allergy & Congestion

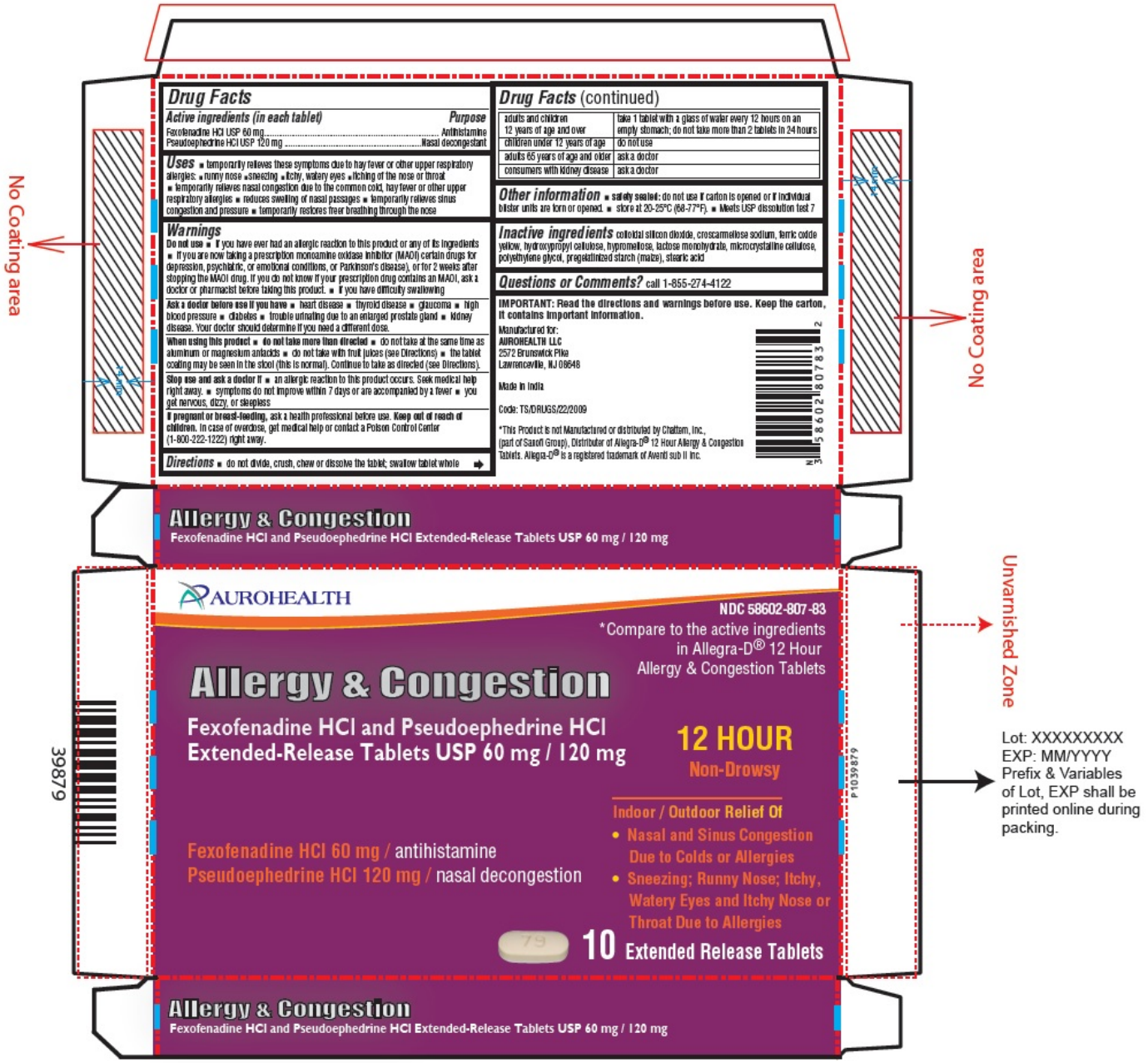
Fexofenadine HCl and Pseudoephedrine HCl
Extended-Release Tablets USP 60 mg / 120 mg

Fexofenadine HCl 60 mg / antihistamine
Pseudoephedrine HCl 120 mg / nasal decongestion

12 HOUR
Non-Drowsy

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**

10 Extended Release Tablets



FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-807
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	YELLOW (White to Off White Layer and Yellow to Pale Yellow)	**Score**	no score
Shape	CAPSULE (Bincovex)	**Size**	19mm
Flavor		**Imprint Code**	Z;79
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-807-83	1 in 1 CARTON	10/30/2017	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-807-67	2 in 1 CARTON	10/30/2017	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:58602-807-84	3 in 1 CARTON	10/30/2017	
3		10 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	ANDA209116	10/30/2017	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-807) , MANUFACTURE(58602-807)

Revised: 6/2024 Aurohealth LLC