

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

**Aurohealth LLC**

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**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<sup>®</sup> 12 Hour  
Allergy & Congestion Tablets

**Allergy & Congestion**

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

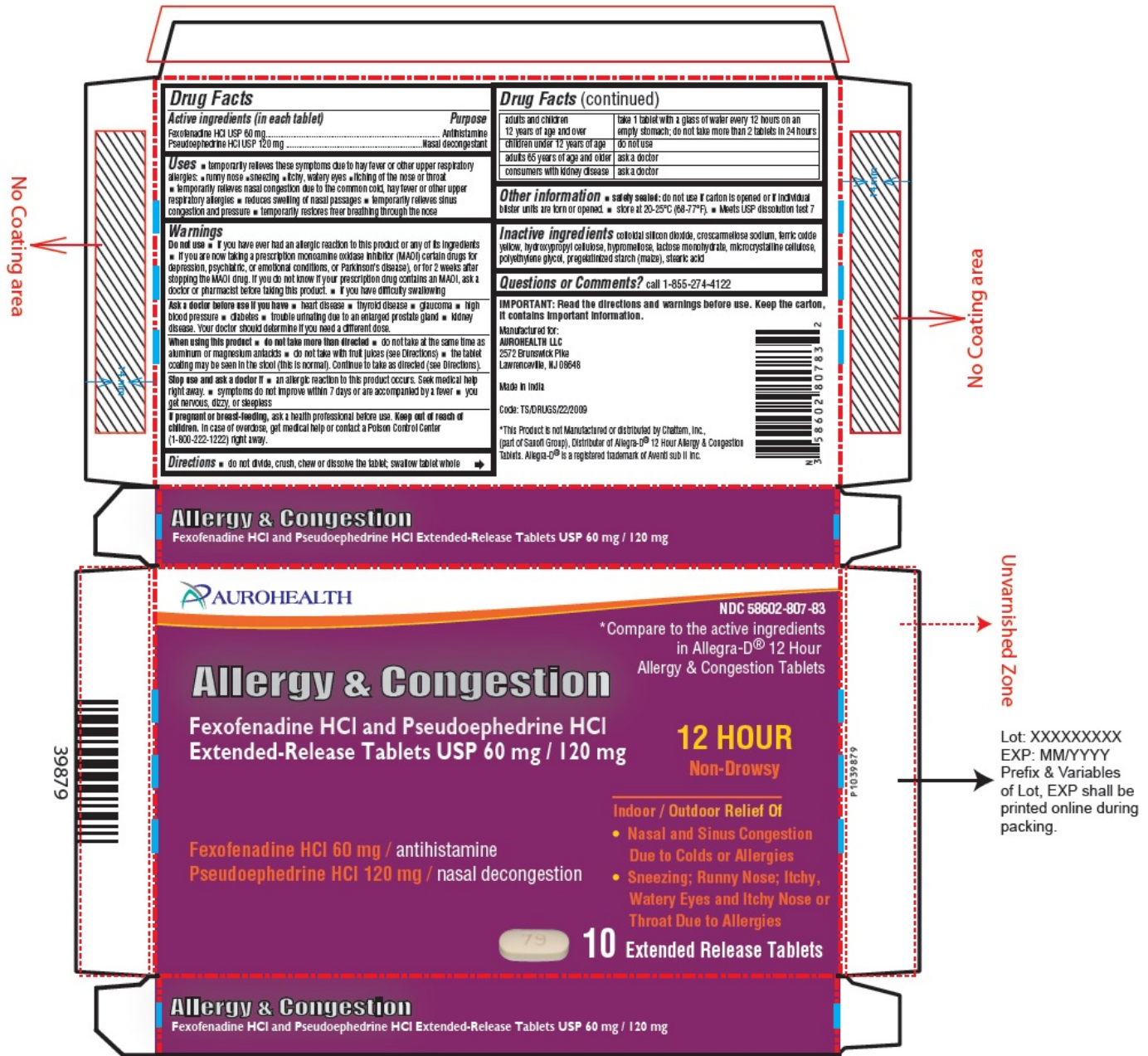
**Fexofenadine HCl 60 mg / antihistamine**  
**Pseudoephedrine HCl 120 mg / nasal decongestion**

**12 HOUR**  
**Non-Drowsy**

**Indoor / outdoor Relief Of**

- **Nasal and Sinus Congestion Due to Colds or Allergens**
- **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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-807
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>FEXO FENADINE HYDRO CHLORIDE</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg
<b>PSEUDOEPHEDRINE HYDRO CHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>HYPROMELLOSE 2208 (100000 MPA.S)</b> (UNII: VM7F0B23ZI)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>HYDROXYPROPYL CELLULOSE (110000 WAMW)</b> (UNII: 5Y0974F5PW)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	YELLOW (White to Off White Layer and Yellow to Pale Yellow)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Binconvex)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	Z;79
<b>Contains</b>			

### 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)

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

Revised: 2/2020

Aurohealth LLC