

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

**AmeriSource Bergen**

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

**Active ingredient(s)**

*(in each extended-release 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)

**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 inner safety seal is open or torn

- store between 20° to 25°C (68° to 77°F)
- USP dissolution test is pending.

### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, ethyl cellulose, ferric oxide yellow, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid.

### **Questions?**

Call toll free 1-800-818-4555 weekdays

Distributed By AmerisourceBergen  
1300 Morris Drive, Chesterbrook, PA 19087

### **PRINCIPAL DISPLAY PANEL - 60 mg/120 mg Tablet Blister Pack Carton**

**GOOD  
NEIGHBOR  
PHARMACY®**

**Compare to Allegra-D® active ingredients\*\***

**NDC 46122-452-60**

***Original Prescription Strength***

**NON-DROWSY**

**12 HOUR**

**fexofenadine HCl 60 mg/antihistamine  
pseudoephedrine HCl 120 mg/nasal decongestant  
Extended-Release Tablets, USP**

***Indoor & Outdoor Allergies***

Allergy & Congestion

**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**

**20 Extended-Release Tablets**

**Drug Facts (continued)**

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)

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 right away (1800-222-1222).

**Drug Facts (continued)**

**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**

- 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)
- USP dissolution test is pending.

**Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, ethyl cellulose, ferric oxide yellow, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid.

**Questions or comments?**  
Call toll-free 1-800-818-4555 weekdays



fexofenadine HCl 60 mg/antihistamine  
pseudoephedrine HCl 120 mg/nasal decongestant  
Extended-Release Tablets, USP



MADE IN INDIA  
Visit us at [www.MfGMP.com](http://www.MfGMP.com)  
Questions or Concerns?  
1300 Morris Drive, Chestersburg, PA 19087  
Distributed By AmerisourceBergan



Compare to Allegra-D® active ingredients™

NDC 46122-452-60

Original Prescription Strength

NON-DROWSY **12 HOUR**  
fexofenadine HCl 60 mg/antihistamine  
pseudoephedrine HCl 120 mg/nasal decongestant  
Extended-Release Tablets, USP

**Indoor & Outdoor Allergies**

Allergy & Congestion

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

20 Extended-Release Tablets



Expiration Date:

NON VARINISH

Batch No.

fexofenadine HCl 60 mg/antihistamine  
pseudoephedrine HCl 120 mg/nasal decongestant  
Extended-Release Tablets, USP  
**Indoor & Outdoor Allergies**  
Allergy & Congestion  
20 Extended-Release Tablets

**Drug Facts**

**Active ingredients** *Purpose*  
(in each extended-release tablet)  
Fexofenadine HCl, USP 60 mg.....Antihistamine  
Pseudoephedrine HCl, USP 120 mg.....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

**Drug Facts (continued)**

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

# HYDROCHLORIDE

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

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46 122-452
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

## Product Characteristics

Color	WHITE, YELLOW	Score	no score
Shape	CAPSULE (bilayer)	Size	17mm
Flavor		Imprint Code	724
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46 122-452-60	1 in 1 CARTON	03/01/2018	
1		20 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
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ANDA	ANDA090818	03/01/2018	
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**Labeler** - AmeriSource Bergen (007914906)

**Establishment**

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(46122-452) , MANUFACTURE(46122-452)

Revised: 5/2018

AmeriSource Bergen