

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

CVS Pharmacy

**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: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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

CVSHealth™

Compare to the active ingredients in Allegra-D®*

Indoor & Outdoor Allergies

Original Prescription Strength

ALLERGY & CONGESTION RELIEF

Allergy Relief D

FEXOFENADINE HCl 60 mg/Antihistamine

PSEUDOEPHEDRINE HCl 120 mg/Nasal decongestant

EXTENDED RELEASE TABLETS, USP

12

HOUR

12 Hour Relief of:

- Nasal & sinus congestion due to colds or allergies
- Sneezing; Runny nose; Itchy, watery eyes & Itchy nose or throat due to allergies

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN

Non-Drowsy

20 EXTENDED-RELEASE TABLETS

Actual Size

GLUE - NO COATING

NO COATING

NO COATING

5186127

5186127

Drug Facts (continued)

Ask a doctor before use if you have

- heart disease
- thyroid disease
- glaucoma
- high blood pressure
- diabetes
- 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 (number on label).

(1-800-222-1222)

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

Drug Facts

Active ingredients
(in each extended-release tablet)

Fexofenadine HCl USP, 60 mg
Pseudoephedrine HCl USP, 120 mg
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
- temporarily relieves sinus congestion and pressure

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

Directions

Temporarily restores nasal breathing through the nose

Other Information

- do not use if carton is opened or if individual blister units are torn or opened
- USP dissolution test is pending.

Inactive ingredients

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

CVS Health Compare to the active ingredients in Allegra-D®*

Indoor & Outdoor Allergies

Original Prescription Strength
ALLERGY & CONGESTION RELIEF
Allergy Relief D
FEXOFENADINE HCl 60 mg/Antihistamine
PSEUDOEPHEDRINE HCl 120 mg/Nasal decongestant
EXTENDED RELEASE TABLETS, USP

12 Hour Relief of:

- Nasal & sinus congestion due to colds or allergies
- Sneezing; Runny nose; Itchy, watery eyes & Itchy nose or throat due to allergies

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN

Non-Drowsy

20 EXTENDED-RELEASE TABLETS

Actual Size

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V-13977

CVS Quality
Money Back Guarantee

0618

#965239

PG SB0899

Expiration Date:
Batch No.

NON VARNISH

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:69842-990
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:7CUC9DD19F)	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	OVAL (bilayer)	Size	17mm
Flavor		Imprint Code	724
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-990-20	1 in 1 CARTON	03/01/2018	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69842-990-30	1 in 1 CARTON	03/01/2018	
2		30 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	ANDA090818	03/01/2018	

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(69842-990) , MANUFACTURE(69842-990)

Revised: 5/2018

CVS Pharmacy