

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

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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

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CVS.com® 1-800-SHOP CVS

Made in India

Code: TS/DRUGS/22/2009

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 2 x 10 Blister Carton**

**CVSHealth®**

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

**NDC 51316-007-67**

**Non-Drowsy  
ALLERGY & CONGESTION RELIEF  
Allergy Relief D**

**Fexofenadine HCl 60 mg/Antihistamine  
PSEUDOEPHEDRINE HCl 120 mg / Nasal decongestant  
EXTENDED-RELEASE TABLETS, USP**

**12  
HOUR**

**INDOOR/OUTDOOR RELIEF OF:**

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

**20 EXTENDED-RELEASE TABLETS**

Actual Size



## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-007
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<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 (Bincovex)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	Z;79
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51316-007-67	2 in 1 CARTON	11/17/2022	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51316-007-84	3 in 1 CARTON	11/17/2022	
2		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	11/17/2022	

**Labeler** - CVS Pharmacy, Inc. (062312574)

**Registrant** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(51316-007) , MANUFACTURE(51316-007)

Revised: 6/2024

CVS Pharmacy, Inc.