FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE - fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release
WALGREEN CO.

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.

DISTRIBUTED BY:
WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
walgreens.com

MADE IN INDIA
Code: TS/DRUGS/22/2009

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

Walgreens

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

NDC 0363-0094-67

NON-DROWSY
Allergy Relief D12
ALLERGY & CONGESTION

Fexofenadine HCl USP 60 mg / Antihistamine
Pseudoephedrine HCl USP 120 mg / Nasal decongestant

12 Hour
Extended-Release Tablets USP

Indoor & Outdoor Allergies
- **Nasal and sinus congestion due to colds or allergies**
- **Relief of sneezing; runny nose; itchy, watery eyes and itchy nose or throat due to allergies**

20 EXTENDED-RELEASE TABLETS


Walgreens
Compare to the active ingredients in Allegra-D® 12 Hour Allergy & Congestion Tablets*
NON-DROWSY
Allergy Relief D12
ALLERGY & CONGESTION
Fexofenadine HCl USP 60 mg / Antihistamine
Pseudoephedrine HCl USP 120 mg / Nasal decongestant
12 Hour
Extended-Release Tablets USP
Indoor & Outdoor Allergies
• Nasal & sinus congestion due to colds or allergies
• Relief of sneezing; runny nose; itchy, watery eyes & itchy nose or throat due to allergies
20 EXTENDED-RELEASE TABLETS
ACTUAL SIZE
NDC 0363-0044-67
W3ORGMMYY-F
LM-4614
P1044661
No Varnish Area
44661
Drug Facts
Active Ingredients (in each tablet) Purpose
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 ■ 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).
Drug Facts (continued)
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
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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
*Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.
†This product is not manufactured or distributed by Aventisub LLC, owner of the registered trademark Allegra-D®.
IMPORTANT: Read the directions and warnings before use. Keep the carton, it contains important information.
Code: TS/DRUGS/22/2009
PAPER BOX
MULTI-LAYER TRAY
how2recycle.info
DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
walgreens.com
©2021 Walgreen Co.
MADE IN INDIA
ITEM 126445 W00000-0000-0
3 11917 02846 0

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:0363-0094
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:0363-0094-67	2 in 1 CARTON	10/30/2017	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-	2 in 1 CARTON	10/30/2017	

2	0094-84	3 in 1 CARTON	10/30/2017	
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	10/30/2017	

Labeler - WALGREEN CO. (008965063)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(0363-0094) , MANUFACTURE(0363-0094)

Revised: 6/2024 WALGREEN CO.