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

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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.**

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
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
*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: 8/2022 WALGREEN CO.