

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

**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?

1-800-632-6900

**DISTRIBUTED BY
THE KROGER CO.
CINCINNATI,
OHIO 45202**

MADE IN INDIA

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 3 x 10 Blister Carton

**COMPARE TO the active ingredients of ALLEGRA-D® 12 HOUR
ALLERGY & CONGESTION TABLETS** *See bottom panel

NDC 30142-

059-84

**Kroger®
Non-Drowsy
Allergy & Congestion**

**Fexofenadine HCl and
Pseudoephedrine HCl
Extended-Release
Tablets USP 60 mg / 120 mg**

**Fexofenadine HCl
60 mg / Antihistamine
Pseudoephedrine HCl
120 mg / Nasal Decongestant**

**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

actual size

30 EXTENDED RELEASE TABLETS

Lot: XXXXXXXXX
EXP: MM/YYYY
Prefix & Varnishes
of Lot, EXP shall be
printed online during
packing.

No Varnish Area

435599

PLEASE RECYCLE

Allegra-D[®] is a registered trademark of Aventis LLC. The Kroger Co. or this product.

IMPORTANT: Read the directions and warnings before use. Keep the carton, it contains important information.

DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202

MADE IN INDIA

For More Product Information, Scan UPC Using Your Kroger App or Call 800-632-6900

Codex: TS/RUCS/22/2009

100% FOR POSITION ONLY
0 41260 01221 1

435599

Drug Facts

Active ingredients (in each tablet)
Fexofenadine HCl USP 60 mg
Pseudoephedrine HCl USP 120 mg

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 relieves throat 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 medicine or other medicine (MAD) certain drugs for depression, psychiatric, or emotional conditions, or Parkinson disease), or 2 weeks after stopping the MAD drug, if you do not know if your prescription drug contains an MAD, ask a doctor or pharmacist before taking this product. ■ If you have difficulty swallowing.

■ **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).

■ **Do not take if:** ■ you are pregnant, breastfeeding, or trying to get pregnant. ■ you are taking other medicine or medicine (MAD) for high blood pressure, heart disease, or thyroid disease ■ you are taking medicine for prostate problems or if individual letter units are torn or opened. ■ store at 20-25°C (68-77°F). ■ Meets USP description test 7

Other information ■ **Sealing:** sealed; do not use if carton is opened or if individual letter units are torn or opened. ■ **Storage:** store at 20-25°C (68-77°F). ■ **Meets USP description test 7**

Inactive ingredients coated tablet: silicon dioxide, croscarmellose sodium, microcrystalline cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose, polyethylene glycol, polydioxane starch (mass), stearic acid

Questions or Comments? 1-800-632-6900

Drug Facts (continued)

Purpose ■ Antihistamine ■ Nasal decongestant

Stop use and ask a doctor if ■ an allergic reaction to the 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 dizzy

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 drink, 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

LM-4491
P1043599

Non-Drowsy

Allergy & Congestion

Fexofenadine HCl and Pseudoephedrine HCl
Extended-Release Tablets USP 60 mg / 120 mg

Fexofenadine HCl 60 mg / Antihistamine
Pseudoephedrine HCl 120 mg / Nasal Decongestant

435599

COMPARE TO the active ingredients of ALLEGRA-D[®] 12 HOUR ALLERGY & CONGESTION TABLETS *See bottom panel

NDC 30142-059-8-4

435599

Non-Drowsy

Allergy & Congestion

Fexofenadine HCl and Pseudoephedrine HCl
Extended-Release
Tablets USP 60 mg / 120 mg

Fexofenadine HCl 60 mg / Antihistamine
Pseudoephedrine HCl 120 mg / Nasal Decongestant

actual size

79

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

30 EXTENDED RELEASE TABLETS

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:30142-059
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)	
CROSCARMELOSE 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:30142-059-84	3 in 1 CARTON	03/15/2021	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination		

1		Product		
2	NDC:30142-059-20	2 in 1 CARTON	05/18/2024	
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	03/15/2021	

Labeler - KROGER COMPANY (006999528)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(30142-059) , MANUFACTURE(30142-059)

Revised: 5/2024

KROGER COMPANY