12HR ALLERGY AND CONGESTION RELIEF- fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, extended release
LEADER/ Cardinal Health 110, Inc.

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

Active ingredient(s)

Fexofenadine HCl USP, 60 mg

Pseudoephedrine HCl USP, 120 mg

Purpose

Antihistamine

Nasal decongestant

Use(s)

- 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 relives 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 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 carton is opened or if individual blister units are torn or opened
- store between 20° to 25°C (68° to 77°F) store between 20° to 25°C (68° to 77°F)
- FDA approved dissolution test specifications differ from USP.
- FDA approved organic impurities test procedure differs from USP Procedure 1.

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, ferric oxide (iron oxide yellow), HPMC

2910 / hypromellose (6 Cps), hydroxypropyl cellulose, hypromellose (methocel K100M DC2), macrogol (polyethylene glycol MW 400), macrogol (polyethylene glycol MW 8000), magnesium stearate, microcrystalline cellulose (avicel PH 101), microcrystalline cellulose (avicel PH102), pregelatinized starch.

Questions?

Call toll-free weekdays 9 AM to 8 PM EST Call **1-888-375-3784**

Principal Display Panel

Blister Carton

Glue - No Coating

No Coating Area

FPO 15008716 2

No Coating Area

FPO 15008716 2

LOT

EXP

No Coating Area

FPO 0 96295 14262 4

CIN 6825617

REV 2/23

LEADER™

NDC 70000-0634-1

NON-DROWSY

12HR Allergy & Congestion Relief

Fexofenadine Hydrochloride | Pseudoephedrine Hydrochloride
Extended-Release Tablets, USP 60 mg/120 mg
Antihistamine | Nasal Decongestant

Indoor / Outdoor Relief Of:
- Nasal and Sinus Congestion Due to Colds or Allergies
- Sneezing; Runny Nose; Itchy, Watery Eyes and Itchy Nose or Throat Due to Allergies

20 EXTENDED-RELEASE TABLETS

Actual Size

COMPARE TO ALLEGRA-D® 12 HOUR ALLERGY & CONGESTION active ingredients*

100% Money Back Guarantee

All LEADER™ Brand Products Have A 100% Money Back Guarantee
Return to place of purchase if not satisfied.

CardinalHealth™

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DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6335
Essential to Care® since 1979

Made in India

NON-DROWSY

12HR Allergy & Congestion Relief

LEADER™

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

Drug Facts (continued)

- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

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- 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

Drug Facts (continued)

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

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- do not take at the same time as aluminum or magnesium antacids
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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 right away (1-800-222-1222).

Drug Facts (continued)

Directions

- do not 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
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Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, ferric oxide (iron oxide yellow), HPMC 2910 / hypromellose (6 cps), hydroxypropyl cellulose, hypromellose (methocel K100M CR), macrogol (polyethylene glycol MW 8000), magnesium stearate, microcrystalline cellulose (avicel PH 101), microcrystalline cellulose (avicel PH102), pregelatinized starch.

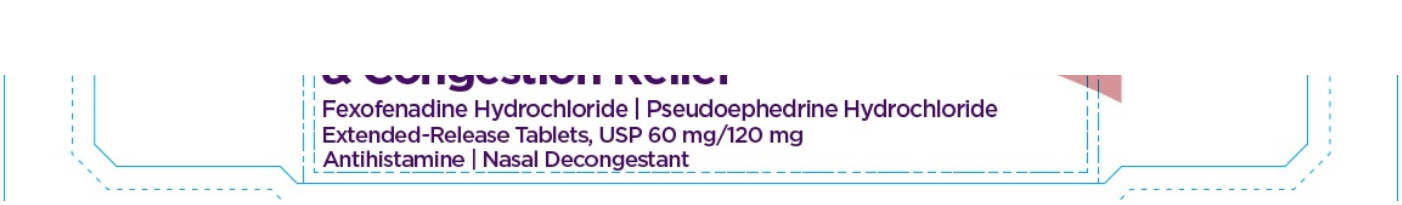
Questions or comments?

call toll-free weekdays 9AM to 8 PM EST Call 1-888-375-3784

*This product is not manufactured or distributed by Chattem, Inc. (parent of the Sanofi group), distributor of Allegra-D® 12 Hour Allergy & Congestion Tablets. Allegra-D® is a registered trademark of Aventis Pharma S.A.

TAMPER EVIDENT: INDIVIDUAL BLISTER UNIT SEALED FOR YOUR PROTECTION.
DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN.

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



12HR ALLERGY AND CONGESTION RELIEF

fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0634
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
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Magnesium Stearate (UNII: 70097M6I30)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Hypromellose 2208 (100000 Mpa.S) (UNII: VM7F0B23ZI)	
HYDROXYPROPYL CELLULOSE (45000 WAMW) (UNII: 8VAB711C5E)	
Hypromellose 2910 (6 Mpa.S) (UNII: 0WZ8WG20P6)	
Polyethylene Glycol 8000 (UNII: Q662QK8M3B)	
Starch, Corn (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	

Product Characteristics

Color	WHITE (one white to off-white color layer and other light yellow to yellow color)	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-	6 in 1 CARTON	05/19/2022	

1	0634-2	6 in 1 CARTON	05/19/2023	
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0634-1	4 in 1 CARTON	05/19/2023	
2		5 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	ANDA215434	03/31/2022	

Labeler - LEADER/ Cardinal Health 110, Inc. (063997360)

Revised: 5/2023 LEADER/ Cardinal Health 110, Inc.