FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE - fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release Strategic Sourcing Services LLC

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Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets USP

#### **Drug Facts**

Active ingredients (in each tablet)

Fexofenadine HCI USP 60 mg Pseudoephedrine HCI 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	take 1 tablet with a glass of water every 12
over	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 833-358-6431 Monday to Friday 9:00am to 7:00pm EST

IMPORTANT: READ THE DIRECTIONS AND WARNINGS BEFORE USE. KEEP THE CARTON, IT CONTAINS IMPORTANT INFORMATION.

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www.fosterandthrive.com

Product of India

Rev. 04/25

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

NDC 70677-1278-1

Foster ξ Thrive<sup>™</sup>

#### **12 HOUR**

COMPARE TO THE ACTIVE INGREDIENTS IN ALLEGRA-D® 12 HOUR ALLERGY & CONGESTION TABLETS\*

Allergy & Congestion-D

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

# ANTIHISTAMINE & NASAL DECONGESTANT Non-Drowsy

#### 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

**ACTUAL SIZE** 

#### **20 EXTENDED RELEASE TABLETS**

#### GLUE - NO COATING

Sourcing Services LLC. Memphis, TN 38141 Money Back Guarantee waw for hearnathrive.com TS3 mq00:T of ms0 009 ysbh3o1yabndM Distributed by: Mt Kes son Corp., vic(Strategic Questions or Comments? an 833-358-6431 cejin plae' boyletinylene glycol, pregelatinized starch (maize), stearic acid вирм, пувтох рюр у селиске, пурготелов, встове пополуския, пистослувания Inactive ingredients collocal silicondicade, croscarmelicae scalum, rerico xo ine babletceatin may be senin the shot (bhk knowna). Continue be bake as descact (see Discribins). #777-89102-5-0518-9108 # Tisef noticios ab 92 U afee M # earled: do not use Toarbon is openedor Tholiwid a bisterunits as bon do :beleasy beta Suborqaild griau marff Betænib marfenom exatton ob m подытиоти тыто

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 you get nervous, dit ay, or sleagues Stop use and sake doctor if an aller gicress fon to this product occurs Seak medbal help right away

Drug Facts (continued)

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Drug Facts (continued)

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NDC 70677-1278-1

Foster & Thrive™

COMPARE TO THE ACTIVE INGREDIENTS IN ALLEGRA-D® 12 HOUR **ALLERGY & CONGESTION TABLETS\*** 

12 HOUR

# Allergy & Congestion-D

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

ANTIHISTAMINE & NASAL DECONGESTANT

Non-Drowsy

#### 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



line not for printir 76 x 18 mm Unvarnished Zone

20 EXTENDED RELEASE TABLETS

Foster & Thrive™

12 HOUR

Allergy & Congestion-D

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



# 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:70677-1278
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: EX43802MRT)		
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				

P	Packaging			
#	Item Code	Package Description Marketing Start Mar Date		Marketing End Date
1	NDC:70677- 1278-1	2 in 1 CARTON	03/05/2025	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination		

	1		Product		
		NDC:70677- 1278-2	3 in 1 CARTON	03/05/2025	
10 in 1 BLISTER PACK; Type 0: Not a Combination Product					

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA209116	03/05/2025	

# **Labeler -** Strategic Sourcing Services LLC (116956644)

## Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(70677-1278), MANUFACTURE(70677-1278)

Revised: 5/2025 Strategic Sourcing Services LLC