

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

**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 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™

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**

**ANTI-HISTAMINE & 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

Drug Facts (continued)

Temporarily relieves nasal congestion and pressure
Temporarily relieves sneezing, itchy, watery eyes, itchy nose or throat
Temporarily relieves sinusitis symptoms due to hay fever or other upper respiratory conditions

Warnings

Do not use if you have a history of allergic reaction to this product or any of its ingredients
If you are taking other prescription or over-the-counter drugs, ask your doctor or pharmacist before taking this product
If you are taking other prescription or over-the-counter drugs, ask your doctor or pharmacist before taking this product
If you are taking other prescription or over-the-counter drugs, ask your doctor or pharmacist before taking this product

Directions

Take 1 tablet with water 12 hours apart
Do not take more than 2 tablets in 24 hours
If you are taking other prescription or over-the-counter drugs, ask your doctor or pharmacist before taking this product

Other Information

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.
If you are taking other prescription or over-the-counter drugs, ask your doctor or pharmacist before taking this product

Questions or Comments? Call 1-833-358-6431

Drug Facts (continued)

Active ingredients (in each tablet)

Fexofenadine HCl USP 120 mg
Pseudoephedrine HCl USP 60 mg

Purpose

Antihistamine
Nasal decongestant

Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory conditions:
Nasal congestion
Sneezing
Itchy, watery eyes
Itchy nose or throat
Runny nose

NDC 70677-1278-1

Foster & Thrive™
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

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



ACTUAL SIZE

20 EXTENDED RELEASE TABLETS

Foster & Thrive™
12 HOUR

Allergy & Congestion-D

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



Rev. 04/25

P1058436

Unvarnished Zone
(dotted line not for printing)
76 x 18 mm

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: 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: 3OIQX730WE)	
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:70677-1278-1	2 in 1 CARTON	03/05/2025	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination		

1		Product		
2	NDC:70677-1278-2	3 in 1 CARTON	03/05/2025	
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	03/05/2025	

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)