

**FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE-
fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, film
coated, extended release
Sun Pharmaceutical Industries, Inc.**

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

Active ingredient(s)

(in each extended-release 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)

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	ask a doctor

Other information

- safety sealed; do not use if inner safety seal is open or torn
- store between 20° to 25°C (68° to 77°F)
- Meets dissolution test 6

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, ethyl cellulose, ferric oxide yellow, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid.

Questions?

Call toll free 1-800-818-4555 weekdays

Principal Display Panel

NDC 47335-724-83

ORIGINAL PRESCRIPTION STRENGTH

NON-DROWSY

Fexofenadine HCl and Pseudoephedrine HCl Extended-Release Tablets, USP

60 mg/120 mg

ALLERGY &

CONGESTION

12 HR

Antihistamine/Nasal Decongestant

Indoor and Outdoor Allergies

30 Tablets

SUN PHARMA

NDC 47335-724-83
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 Antihistamine/Nasal Decongestant
 30 Tablets



Mfg. by: Sun Pharmaceutical Industries Limited India.
 Dist. by: Sun Pharmaceutical Industries, Inc. NJ 08512

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
 DO NOT USE IF INNER SAFETY SEAL IMPRINTED WITH
 "SEALED for YOUR PROTECTION" IS TORN OR MISSING

Drug Facts	
Active ingredients	Purpose
<i>(in each extended-release tablet)</i>	
Fexofenadine HCl, USP 60 mg.....	Antihistamine
Pseudoephedrine HCl, USP 120 mg.....	Nasal Decongestant



Open for Full Labeling →

5 2 3 8 6 1 9

GTIN XXXXXXXXXXXXXXXX
 SN XXXXXXXXX
 LOT AAA##A
 EXP YYYY-MM

Drug Facts (continued)	<p>Uses</p> <ul style="list-style-type: none"> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> 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 <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> 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. <p>When using this product</p> <ul style="list-style-type: none"> 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)
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5 2 3 8 6 1 9

Hinge

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Hinge

Principal Display Panel-Showbox

**NDC 47335-724-94
 ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY**

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

ALLERGY & CONGESTION

12 HR

Antihistamine/Nasal Decongestant




10 Extended-Release Tablets

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

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN
SUN PHARMA

<p>NDC 47335-724-94</p> <p>ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY</p> <p>Fexofenadine HCl and Pseudoephedrine HCl Extended-Release Tablets, USP</p> <p style="background-color: #e91e63; color: white; text-align: center; padding: 5px;">60 mg/120 mg</p> <p>ALLERGY & CONGESTION 12 HR</p> <p>Antihistamine/Nasal Decongestant 10 Extended-Release Tablets</p> <p>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</p> <p>DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN</p>	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">DNRHDSUNH138</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Distributed by: Sun Pharmaceutical Industries, Inc. San Francisco, CA 94103</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Manufactured by: Sun Pharmaceuticals Limited Surat No. 392012, Gujarat, India U.T. of D & NH and Daman & Diu, India.</p>	<p>NDC 47335-724-94</p> <p>ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY</p> <p>Fexofenadine HCl and Pseudoephedrine HCl Extended-Release Tablets, USP</p> <p style="background-color: #e91e63; color: white; text-align: center; padding: 5px;">60 mg/120 mg</p> <p>ALLERGY & CONGESTION 12 HR</p> <p>Antihistamine/Nasal Decongestant 10 Extended-Release Tablets</p> <p>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</p> <p>DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN</p> <p style="text-align: right;"></p>	 <p>5 21 5 2 5</p> 	<p>Drug Facts</p> <p>Active ingredients (in each extended-release tablet)</p> <p>Fexofenadine HCl, USP 60 mg.....Antihistamine Pseudoephedrine HCl, USP 120 mg.....Nasal Decongestant</p> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> runny nose 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 their breathing through the nose itchy, watery eyes <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> heart disease high blood pressure trouble urinating due to an enlarged prostate gland kidney disease. Your doctor should determine if you need a different dose. thyroid disease diabetes glaucoma <p>When using this product</p> <ul style="list-style-type: none"> 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) <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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 	<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use. 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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:47335-724
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75Z U) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

STEARIC ACID (UNII: 4ELV7Z65AP)

HYPROMELLOSES (UNII: 3NXW29V3WO)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

Product Characteristics

Color	WHITE, YELLOW	Score	no score
Shape	CAPSULE (bilayer)	Size	17mm
Flavor		Imprint Code	724
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47335-724-83	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2018	
2	NDC:47335-724-94	1 in 1 CARTON	03/01/2018	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:47335-724-99	2 in 1 CARTON	03/01/2018	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:47335-724-95	3 in 1 CARTON	03/01/2018	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:47335-724-66	2 in 1 CARTON	03/01/2018	
5		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:47335-724-75	4 in 1 CARTON	03/01/2018	
6		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:47335-724-64	6 in 1 CARTON	03/01/2018	
7		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	ANDA090818	03/01/2018	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(47335-724) , MANUFACTURE(47335-724)

Revised: 9/2023

Sun Pharmaceutical Industries, Inc.