

FEXOFENADINE HCL- fexofenadine hcl tablet, film coated
Safrel Pharmaceuticals, LLC.

FEXOFENADINE HYDROCHLORIDE TABLETS USP, 60mg and 180 mg

Allergy

ALLERGY

Active ingredient (in each film-coated tablet)

Fexofenadine HCl USP, 60mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings

Do not use

if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have

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 a doctor if

an allergic reaction to this product occurs. Seek medical help right away.

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 (1800-222-1222).

Directions

FOR 60mg

adults and children 12 years of age and over

take two 60mg tablets with water every 12 hours; 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 printed foil inner seal on bottle is torn or missing
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture
-

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch (maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide and yellow iron oxide.

Questions or comments?

Call 1-844-384-3723

Distributed by:

Safrel Pharmaceuticals, LLC

Bridgewater, NJ 08807

www.safrel.com

Fexofenadine 60 mg

COMPARE TO THE ACTIVE INGREDIENT IN ALLEGRA® ALLERGY 24-HOUR TABLETS*

Safrel® NDC 71309-090-10

NON-DROWSY

ALLERGY RELIEF

Fexofenadine HCL Tablets • 60 mg

ANTIHISTAMINE 12 HR

INDOOR / OUTDOOR

- Sneezing • Runny Nose
- Itchy Nose or Throat
- Watery Eyes

Film Coated

ACTUAL SIZE

100 TABLETS / 60 MG EACH

3 71309 09010 9

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED.

Drug Facts

Active ingredient
(in each film-coated tablet)
Fexofenadine HCl USP 60 mg Antihistamine

Purpose
Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 ■ runny nose ■ itchy, watery eyes
 ■ sneezing ■ itching of the nose or throat

Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have 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 a doctor if an allergic reaction to this product occurs. Seek medical help right away.

LIFT HERE

PEEL FOR WARNINGS & DIRECTIONS

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of an overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- **Adults and children 12 years of age and over:** take (1) one 60 mg tablet with water every 12 hours; do not take more than two (2) tablets in 24 hours
- **Children under 12:** Do not use
- **adults 65 years of age and older** ask a doctor
- **consumers with kidney disease** ask a doctor

Other information

- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture
- each tablet contains: sodium 2.7 mg (for 60mg)
- this product meets the requirements of USP Dissolution Test 2

Inactive ingredients
Anhydrous Lactose, Colloidal Silicon Dioxide, Corn Starch, Croscarmellose Sodium, Lactose Monohydrate, Pregeatinized Starch (Maize), Stearic Acid, Opadry Pink 03b84893 containing Hypromellose, Polyethylene Glycol, Red Iron Oxide, Titanium Dioxide and Yellow Iron Oxide.

Questions? 1-844-384-3723 or safrel.com

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FEXOFENADINE HCL			
fexofenadine hcl tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71309-090
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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	pink	Score	no score
Shape	OVAL (Modified Oval)	Size	12mm
Flavor		Imprint Code	SG;201
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-090-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	12/08/2022	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)

Revised: 7/2023

Safrel Pharmaceuticals, LLC.