

FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet
Safrel Pharmaceuticals, LLC.

Fexofenadine HCl Tablets 180 mg

ACTIVE INGREDIENT(S)

Fexofenadine HCl USP 60 mg (for 60 mg)

Fexofenadine HCl USP 180 mg (for 180 mg)

PURPOSE

Antihistamine

USE(S)

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

- runny nose
- itchy, water 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.

DIRECTIONS

adults and children 12 years of age and over	take one 60 mg tablet with water every 12 hours; do not take more than 2 tablets in 24 hours (for 60 mg) take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours (for 180 mg)
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 foil printed with granules logo under bottle cap is opened or torn.
- Do not use if carton is opened or if individual blister units are torn or opened.
- 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, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide and yellow iron oxide

QUESTIONS OR COMMENTS

Contact 1-844-384-3723 Mon-Fri 8:00 AM EST to 5:00 PM PST

Distributed By:

Safrel Pharmaceuticals, LLC
Bridgewater, NJ 08807

PRINCIPAL DISPLAY PANEL

NDC 71309-091-01 - 100 Count

NDC 71309-091-01

Compare to Allegra® Allergy 24 Hour active Ingredient*

Safrel®

Non-Drowsy

ALLERGY RELIEF

Fexofenadine Hydrochloride Tablets / Antihistamine

24 Hour

Indoor / Outdoor Relief of:

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

180 mg

100 TABLETS 24 HR

Drug Facts		Drug Facts (Continued)	
Active Ingredient.....Purpose (in each film-coated tablet) Fexofenadine HCl 180mg.....Antihistamine		Directions	
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		Adults and children 12 years of age and over	take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours
Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients		Children under 12 years of age	do not use
Ask a doctor before use if you have kidney disease Your doctor should determine if you need a different dose.		Adults 65 years of age and older	ask a doctor
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)		Consumers with kidney disease	ask a doctor
Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away. If pregnant and breast-feeding, ask a health professional before use. Keep out of reach of children. In case of accidental overdose, contact a doctor or Poison Control Center right away.		Other information ■ store at room temperature 20° – 25°C (68° – 77°F) ■ protect from excessive moisture ■ do not use if imprinted seal under safety cap is broken or missing	
		Inactive ingredients anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide and yellow iron oxide	
		Questions Call 1-844-384-3723 Monday through Friday 9AM - 5PM	

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

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Bridgewater, NJ 08807
www.safrelpharma.com



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FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71309-091
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics

Color	orange (PEACH)	Score	no score
Shape	OVAL (Capsule-shaped)	Size	17mm

Flavor		Imprint Code	G6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-091-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211075	01/03/2021	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)

Revised: 3/2023

Safrel Pharmaceuticals, LLC.