

FEXOFENADINE HCL- fexofenadine hcl tablet
Akron Pharma Inc.

Fexofenadine Hydrochloride Tablets USP, 180 mg

ACTIVE INGREDIENT(S), in each tablet

Fexofenadine hydrochloride USP, 180 mg

PURPOSE

Antihistamine

USE(S)

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

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

60 mg

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
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

180 mg

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
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 the 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.

HOW SUPPLIED SECTION

Fexofenadine Hydrochloride Tablets, USP 180 mg 100 CT

NDC: 71399-8042-1

QUESTIONS OR COMMENTS


Call weekdays 8.30 AM to 4.30 PM EST **Please Call 1(877) 225-6999**

Manufactured for:

Akron Pharma, Inc.

Fairfield, NJ 07004

Manufactured in U.S.A



NDC 71399-8042-1

Compare to the active ingredient in Allegra® Allergy 24 Hour Tablets*

Original Prescription Strength, Non-Drowsy

Allergy Relief

Fexofenadine Hydrochloride

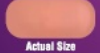
Tablets USP, 180 mg

Antihistamine

INDOOR AND OUTDOOR ALLERGIES

24 Hour Relief Of:

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



100 Tablets

Drug Facts

Active ingredient (in each film-coated tablet)
Fexofenadine HCl USP, 180 mg

Purpose
Antihistamine

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.

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 180 mg tablet with water once a day, do not take more than 1 tablet 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 ■ Store between 20° and 25° C (68° and 77° F) ■ protect from excessive moisture ■ each tablet contains: sodium 8.2 mg ■ this product meets the requirements of USP Dissolution Test 2 ■ Tamper Evident: Do not use if imprinted inner safety seal is torn or missing.

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 toll-free 1-877-225-6999

*This product is not manufactured or distributed by Chatham, Inc. (parent of Allegra® Allergy 24 Hour Tablets). Allegra® is a registered trademark of Aventis Inc.

Akvon Pharma
Distributed by:
Akron Pharmaceuticals
373 RT US 46 W Building E,
Suite 117, Fairfield, NJ 07004
www.akvonpharma.com
Made in USA
Rev. C 08/20

Lot.:
Exp.:

FEXOFENADINE HCL

fexofenadine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-8042
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	PINK	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	SG;202
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-8042-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	09/09/2020	

Labeler - Akron Pharma Inc. (067878881)

Revised: 2/2023

Akron Pharma Inc.