

FEXOFENADINE HYDROCHLORIDE - fexofenadine hydrochloride tablet, film coated
Aphena Pharma Solutions - Tennessee, LLC

Active ingredient(in each tablet)

Fexofenadine HCl USP, 180 mg

Fexofenadine HCl USP, 60 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 aluminium 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.

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

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 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 bottle is torn or missing
- store between 20°and 25°C (68°and 77°F)
- protect from excessive moisture and light

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch,croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol 400, pregelatinized corn starch, red iron oxide, steric acid, titanium dioxide, and yellow iron oxide,

Questions or comments?

call 1-855-274-4122

Repackaging Information

Please reference the ***How Supplied*** section listed above for a description of individual tablets. This

drug product has been received by Aphena Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphena are listed below:

Count	180 mg
30	71610-292-30

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20190607JH

PRINCIPAL DISPLAY PANEL - 180 mg

NDC 71610-292 - Fexofenadine HCl, USP 180 mg Tablets - Rx Only



FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71610-292(NDC:58602-711)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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FEXO FENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)			FEXO FENADINE HYDROCHLORIDE	180 mg
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	ORANGE (Peach)		Score	no score
Shape	CAPSULE (Bevel Edge, Biconvex)		Size	17mm
Flavor			Imprint Code	E;44
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-292-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/06/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA202039		01/15/2015	

Labeler - Aphena Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-292)

Revised: 6/2019

Aphena Pharma Solutions - Tennessee, LLC