

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

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**Drug Facts**

**Active ingredient (in each tablet)**

Fexofenadine hydrochloride 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 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**

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adults and children 12 years of age | take one 60 mg tablet with water every 12 hours; do not take more

and over	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

- Tamper Evident: do not use if foil seal under cap is missing, open or broken
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

### Inactive ingredients

Butylated hydroxyanisole, crospovidone, FD&C Blue No. 1 Aluminum Lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, polysorbate 80, povidone, sodium lauryl sulfate, titanium dioxide and triacetin.

### Questions or comments?

Call **1-877-446-3679 (1-877-4-INFO-RX)**

Manufactured by: **Mylan Pharmaceuticals Inc.**, Morgantown, WV 26505 U.S.A.

Marketed/ Packaged by: **GSMS, Inc.**, Camarillo, CA 93012 USA

### Repackaging Information

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

Count	180 mg
30	43353-760-30
60	43353-760-53
90	XXXXX-XXX-60
120	XXXXX-XXX-70
180	XXXXX-XXX-80
240	XXXXX-XXX-90
270	XXXXX-XXX-92

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

20171201JH

**PRINCIPAL DISPLAY PANEL - 180mg**

NDC 43353-760 - Fexofenadine HCl 180mg - Rx Only



**FEXOFENADINE HYDROCHLORIDE**  
fexofenadine tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43353-760(NDC:60429-389)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

### Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL (caplet-shaped)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	M;755
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43353-760-53	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/09/2014	
2	NDC:43353-760-60	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077081	03/20/2014	

**Labeler** - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

### Establishment

Name	Address	ID/FEI	Business Operations
Golden State Medical Supply, Inc.		603184490	REPACK(43353-760)

Revised: 12/2017

Aphenia Pharma Solutions - Tennessee, LLC