

**FEXOFENADINE HYDROCHLORIDE - fexofenadine hydrochloride tablet, film coated**  
**Aurohealth LLC**

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**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

## Principal Display Panel

**NDC 58602-711-19**

**\*Compare to 24 Hour Allegra®  
Allergy active ingredient**

**Original Prescription Strength Non-Drowsy**

**Fexofenadine Hydrochloride Tablets USP, 180 mg/antihistamine**

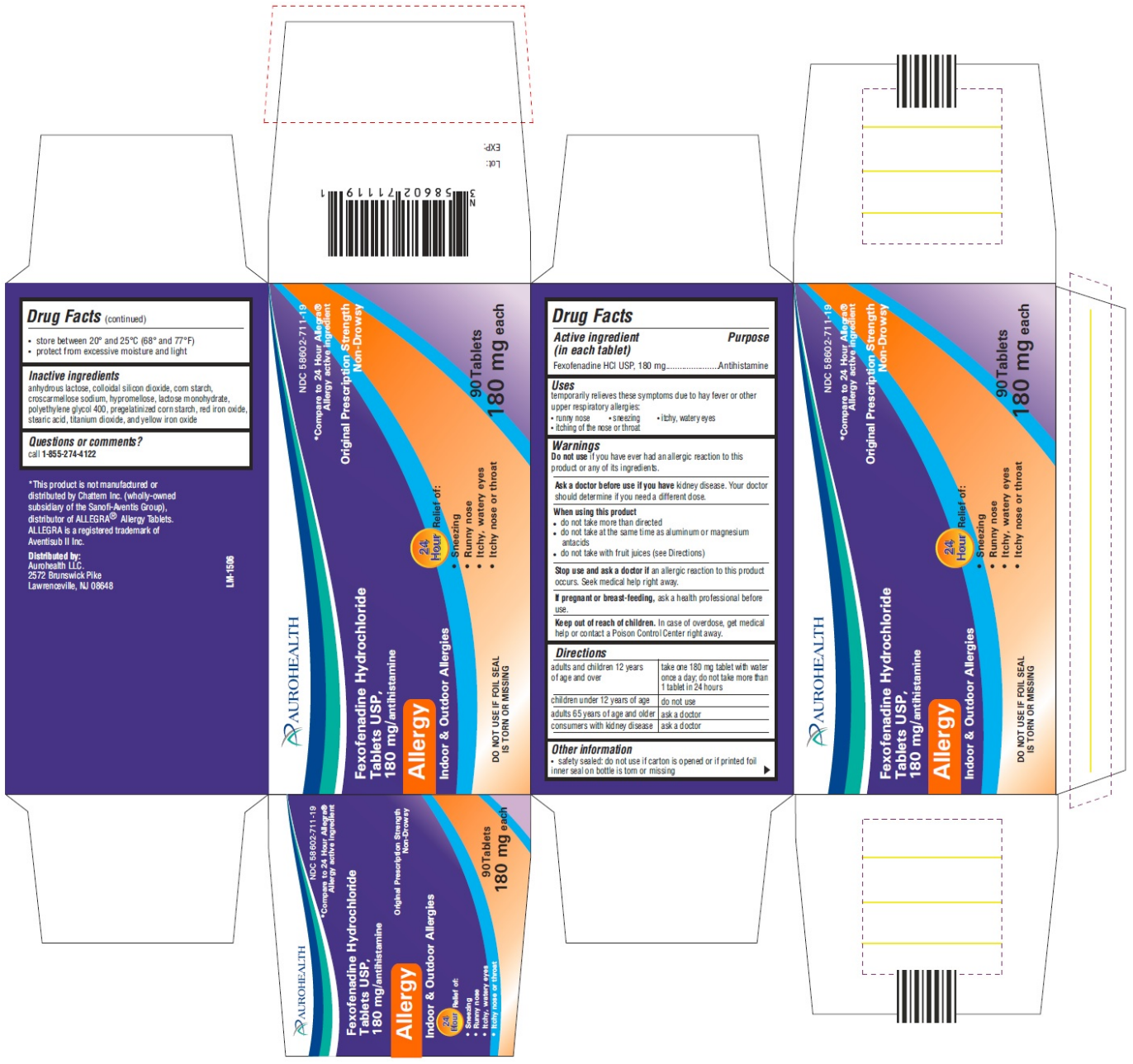
**Allergy  
Indoor & Outdoor Allergies**

**24 Hours Relief of:**

**Sneezing  
Runny nose  
Itchy, Watery Eyes  
Itchy Nose or Throat**

**DO NOT USE IF FOIL SEAL IS TORN OR MISSING**

**90 Tablets 180 mg each**



**Principal Display Panel**

**NDC 58602-710-40**

**\*Compare to 12 Hour Allegra®  
Allergy active ingredient**

**Original Prescription Strength Non-Drowsy**

# Fexofenadine Hydrochloride Tablets USP, 60 mg/antihistamine

Allergy  
Indoor & Outdoor Allergies

12 Hours Relief of:

Sneezing  
Runny nose  
Itchy, Watery Eyes  
Itchy Nose or Throat

DO NOT USE IF FOIL SEAL IS TORN OR MISSING

500 Tablets 60 mg each

**Drug Facts**

**Active ingredient (in each tablet)** Fexofenadine HCl USP, 60 mg. Antihistamine

**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 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

**Other information** • do not use if foil seal 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, stearic acid, titanium dioxide, and yellow iron oxide

**Questions or comments?** call 1-855-274-4122

\*This product is not manufactured or distributed by Chemim Inc. (wholly-owned subsidiary of the Smith-Avants Group, distributor of ALLEGRA® Allergy Tablets. ALLEGRA is a registered trademark of Aventis-B.B. Inc.

**Distributed by:**  
Aurohealth LLC  
2572 Brunswick Pike  
Lawrenceville, NJ 08648

Lot: \_\_\_\_\_  
EXP: \_\_\_\_\_

Principal Display Panel

NDC 58602-710-40

\*Compare to 12 Hour Allegra®  
Allergy active ingredient

Original Prescription Strength Non-Drowsy

Fexofenadine Hydrochloride Tablets USP, 60 mg/antihistamine

**Allergy**  
**Indoor & Outdoor Allergies**

**12 Hours Relief of:**

**Sneezing**  
**Runny nose**  
**Itchy, Watery Eyes**  
**Itchy Nose or Throat**

**DO NOT USE IF FOIL SEAL IS TORN OR MISSING**

**12 Tablets 60 mg each**

LEBG74902

**Drug Facts**

**Active ingredient (in each tablet)**

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 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
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 individual blister units are torn or opened
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture and light

**Drug Facts (continued)**

**Inactive ingredients**

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

**Questions or comments?** call 1-855-274-4122

LM-3312



NDC 58602-710-75

\* Compare to 12 Hour Allegra® Allergy active ingredient

Original Prescription Strength Non-Drowsy

# Allergy

Indoor & Outdoor Allergies  
Fexofenadine Hydrochloride  
Tablets USP,  
60 mg/antihistamine

12 Hour

**Relief of:**

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy nose or throat

12 Tablets  
60 mg each

DO NOT USE IF FOIL SEAL IS TORN OR MISSING



## Allergy

Indoor & Outdoor Allergies  
Fexofenadine Hydrochloride Tablets USP,  
180 mg/antihistamine

Lot:  
EXP:

Distributed by:  
Aurohealth LLC,  
2572 Brunswick Pike  
Lawrenceville, NJ 08648

\*This product is not manufactured or distributed by Chatter Inc., (wholly-owned subsidiary of the Sanofi-Aventis Group), distributor of ALLEGRA® Allergy Tablets. ALLEGRA is a registered trademark of Aventisub II Inc.



### FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-711
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ANHYDRO US LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIO XIDE (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 DIO XIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	ORANGE (Peach)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Bevel Edge, Biconvex)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	E;44
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-711-19	1 in 1 CARTON	01/15/2015	
1		90 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-711-21	1 in 1 CARTON	01/15/2015	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA202039	01/15/2015	



# FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-710
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXO FENADINE - UNII:E6582LOH6V)	FEXO FENADINE HYDROCHLORIDE	60 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ANHYDRO US LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, 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

<b>Color</b>	ORANGE (peach)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Bevel Edge,Bioconvex)	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	E;42
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-710-40	1 in 1 CARTON; Type 0: Not a Combination Product	10/05/2016	
2	NDC:58602-710-75	1 in 1 CARTON; Type 0: Not a Combination Product	10/05/2016	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA202039	10/05/2016	

**Labeler** - Aurohealth LLC (078728447)

**Establishment**

Name	Address	ID/FEI	Business Operations
Aurolife Pharma, LLC		829084461	MANUFACTURE(58602-710, 58602-711)

Revised: 9/2019

Aurohealth LLC