

**12HR ALLERGY RELIEF- fexofenadine hydrochloride tablet**  
**CARDINAL HEALTH**

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**1191A-LEA-2021-0924**

***Drug Facts***

**Active ingredient (in each tablet)**

Fexofenadine HCl 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 (1-800-222-1222).

**Directions**

adults and children	take one 60 mg tablet with water every 12
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12 years of age and over	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**

- store between 20-25°C (68-77°F)
- protect from excessive moisture
- retain carton for complete product information and warnings

### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide

### **PRINCIPAL DISPLAY PANEL**

LEADER™

NDC 70000-0586-1

NON-DROWSY

12 HR Allergy Relief

Fexofenadine Hydrochloride Tablets, 60 mg

Antihistamine

Indoor/Outdoor Relief of:

Sneezing; Runny Nose; Itchy, Watery Eyes;

Itchy Nose or Throat

12 TABLETS

Actual Size

COMPARE TO ALLEGRA® 12 HOUR ALLERGY active ingredient\*

100% Money Back Guarantee

NON-DROWSY

# 12HR Allergy Relief

Fexofenadine Hydrochloride Tablets, 60 mg / Antihistamine



FBIHQZLEA\_R0 CIN 5737465 REV. 9/21

0 96295 14147 4

**Drug Facts**  
**Active ingredient**  
 Fexofenadine HCl 60 mg.....Antihistamine

**Purpose**  
 temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
 ■ sneezing  
 ■ runny nose  
 ■ 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.

**Uses**  
 temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
 ■ sneezing  
 ■ runny nose  
 ■ itchy, watery eyes  
 ■ itching of the nose or throat

**Do not use if you have ever had an allergic reaction to this product or any of its ingredients.**

**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 (1-800-222-1222).

**Drug Facts (continued)**

**Directions**  
 adults and children  
 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**  
 ■ store between 20-25°C (68-77°F)  
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**Inactive ingredients**  
 colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide

**Questions or comments?**  
 1-844-705-4384

**Other information**  
 ■ store between 20-25°C (68-77°F)  
 ■ protect from excessive moisture  
 ■ retain carton for complete product information and warnings

\* This product is not manufactured or distributed by Chatterm, Inc., distributor of Allegra® 12 Hour Allergy.

DISTRIBUTED BY CARDINAL HEALTH  
 DUBLIN, OHIO 43007  
 www.myleader.com 1-800-200-6315  
 Made in India

**DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN**

**ALL LEADER™ Brand Products Have a 100% Money Back Guarantee**  
 Return to place of purchase if not satisfied.

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NON-DROWSY

# 12HR Allergy Relief

Fexofenadine Hydrochloride Tablets, 60 mg / Antihistamine



NDC 70000-0586-1

NON-DROWSY

# 12HR Allergy Relief

Fexofenadine Hydrochloride Tablets, 60 mg  
Antihistamine

Indoor / Outdoor Relief of:  
 Sneezing; Runny Nose; Itchy, Watery Eyes;  
 Itchy Nose or Throat

# 12 TABLETS



Actual Size

**COMPARE TO ALLEGRA® 12 HOUR ALLERGY active ingredient\***

100% Money Back Guarantee

# 12HR ALLERGY RELIEF

fexofenadine hydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0586
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>HYPROMELLOSE 2910 (15 MPA.S)</b> (UNII: 36SFW2JZ0W)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	orange ((PEACH))	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	G5
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0586-1	1 in 1 CARTON	09/24/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA211075	09/24/2021	

**Labeler** - CARDINAL HEALTH (063997360)

Revised: 9/2021

CARDINAL HEALTH