

**FEXOFENADINE HCL- fexofenadine hcl tablet, film coated**  
**Major Pharmaceuticals**

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**ALLERGY**

**Active ingredient (in each film-coated tablet)**

Fexofenadine HCl USP 60 mg  
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 (1-

800-222-1222).

## Directions

### Directions (for 60mg)

adults and children 12 years of age and over	take one 60mg 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

### Directions (for 180mg)

adults and children 12 years of age and over	take one 180mg 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 2.7 mg (for 60 mg), sodium 8.2 mg (for 180 mg)
- this product meets the requirements of USP *Dissolution Test 2*

## Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide

## Questions or comments?

Call toll-free **1-888-588-1418**  
Monday-Friday 9AM-7PM EST

Distributed by: **MAJOR® PHARMACEUTICALS**  
Indianapolis, IN 46268  
**(800) 616-2471**  
www.majorpharmaceuticals.com

**Package/Label Principal Display Panel**

**MAJOR<sup>®</sup>**

**NDC 0904-7192-04**

Compare to the  
active ingredient in  
Allegra<sup>®</sup> Allergy<sup>\*</sup>

**Non-Drowsy**

**Fexofenadine Hydrochloride  
Tablets, USP**

**60 mg**

**Antihistamine**

**12-Hour**

**Indoor/Outdoor Allergy Relief**

■ Sneezing ■ Runny Nose

■ Itchy, Watery Eyes ■ Itchy Nose or Throat

**100 Tablets**

**Allergy Relief**

**MAJOR**<sup>®</sup>

NDC 0904-7192-04

Compare to the active ingredient in Allegra<sup>®</sup> Allergy \*

Non-Drowsy

**Fexofenadine Hydrochloride Tablets, USP**

**60 mg**

Antihistamine

12-Hour Indoor/Outdoor Allergy Relief

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

**100 Tablets**

**Allergy Relief**

**TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDERCAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING**

**Drug Facts**

**Active ingredient (in each film-coated tablet)**  
Fexofenadine HCl USP, 60 mg

**Purpose**  
Antihistamine

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

(Continued On Back Of Label)

\*This product is not manufactured or distributed by Chatterm, Inc, a Sanofi Company, distributor of Allegra<sup>®</sup> Allergy

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Rev. 07/24 M-174 Re-order No. 701402



**NO VARNISH  
0.3" x 1.2"**



**ADHESIVE AREA**

**Questions or comments?** Call toll-free 1-888-588-1418 Monday-Friday 9AM-7PM EST

**Inactive ingredients** anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide

**Dissolution Test 2**

**Other Information**  
■ store between 20° and 25°C (68° to 77°F) ■ protect from excessive moisture ■ each tablet contains: sodium 2.7 mg ■ this product meets the requirements of USP

**ask a doctor**

**ask a doctor**

**ask a doctor**

**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

**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).

**If pregnant or breast-feeding,** ask a health professional before use.

**Stop use and ask a doctor if an allergic reaction to this product occurs.** Seek medical help right away.

**Drug Facts (continued)**

**ADHESIVE AREA**

**MAJOR**<sup>®</sup>

**NDC 0904-7192-60**

Compare to the active ingredient in Allegra<sup>®</sup> Allergy \*

**Non-Drowsy**

**Fexofenadine Hydrochloride Tablets, USP**

**60 mg**

**Antihistamine**

**12-Hour**

**Indoor/Outdoor Allergy Relief**

■ Sneezing ■ Runny Nose

■ Itchy, Watery Eyes ■ Itchy Nose or Throat

**100 Tablets**  
**Allergy Relief**

<p><b>MAJOR®</b></p> <p><b>Non-Drowsy</b></p> <p><b>Fexofenadine Hydrochloride Tablets, USP</b></p> <p><b>60 mg</b></p> <p><b>Antihistamine</b></p> <p><b>12-Hour</b> Indoor/Outdoor Allergy Relief</p> <ul style="list-style-type: none"> <li>• Sneezing • Runny Nose</li> <li>• Itchy, Watery Eyes • Itchy Nose or Throat</li> </ul> <p><b>100 Tablets</b>    <b>Allergy Relief</b></p>	<p>NDC 0904-7192-60</p> <p>Compare to the active ingredient in Allegra® Allergy*</p> <p><b>TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDERCAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING</b></p>	<p><b>Drug Facts</b></p> <p><b>Active Ingredient (in each film-coated tablet)</b> Fexofenadine HCl USP: 60 mg</p> <p><b>Purpose</b> Antihistamine</p> <p><b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <input type="checkbox"/> runny nose <input type="checkbox"/> itchy, watery eyes <input type="checkbox"/> sneezing <input type="checkbox"/> itching of the nose or throat</p> <p><b>Warnings</b> Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p><b>Ask a doctor before use if you have</b> kidney disease. Your doctor should determine if you need a different dose.</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>do not take more than directed</li> <li>do not take at the same time as aluminum or magnesium antacids</li> <li>do not take with fruit juices (see Directions)</li> </ul>	<p>(Continued On Back Of Label)</p> <p>This product is not manufactured or distributed by Chatterm, Inc, a Sanofi Company, distributor of Allegra® Allergy</p> <p>Distributed by: <b>MAJOR® PHARMACEUTICALS</b> Indianapolis, IN 46268 (800) 616-2471 www.majorpharmaceuticals.com Rev. 07/24 M-174 Re-order No. 701294</p> <p><b>NO VARNISH</b> <b>0.3" x 1.2"</b></p>
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<p><b>ADHESIVE AREA</b></p>	<p><b>Questions or comments?</b> Call toll-free 1-888-588-1418 Monday-Friday 9AM-7PM EST</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if an allergic reaction to this product occurs.</b> Seek medical help right away.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p><b>Directions</b> <input type="checkbox"/> <b>adults and children 12 years of age and over</b> take one 60 mg tablet with water every 12 hours; do not take more than 2 tablets in 24 hours <input type="checkbox"/> <b>children under 12 years of age</b> do not use <input type="checkbox"/> <b>adults 65 years of age and older</b> ask a doctor <input type="checkbox"/> <b>consumers with kidney disease</b> ask a doctor</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store between 20° and 25°C (68° to 77°F) <input type="checkbox"/> protect from excessive moisture <input type="checkbox"/> each tablet contains: sodium 2.7 mg <input type="checkbox"/> this product meets the requirements of USP Dissolution Test 2</li> </ul> <p><b>Inactive ingredients</b> anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide</p>	<p><b>ADHESIVE AREA</b></p>
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**MAJOR®**  
**NDC 0904-7192-40**  
Compare to the active ingredient in Allegra® Allergy\*  
**Non-Drowsy**  
**Fexofenadine Hydrochloride Tablets, USP**  
**60 mg**  
**Antihistamine**  
**12-Hour**

# Indoor/Outdoor Allergy Relief

■ Sneezing ■ Runny Nose

■ Itchy, Watery Eyes ■ Itchy Nose or Throat

500 Tablets

Allergy Relief

**MAJOR®** NDC 0904-7192-40  
Compare to the active ingredient in Allegra® Allergy\*  
**Non-Drowsy**  
**Fexofenadine Hydrochloride Tablets, USP**  
**60 mg**  
**Antihistamine**  
**12-Hour Indoor/Outdoor Allergy Relief**  
• Sneezing • Runny Nose  
• Itchy, Watery Eyes • Itchy Nose or Throat  
**500 Tablets** **Allergy Relief**

**TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDERCAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING**

Active Ingredient (in each film-coated tablet)	Purpose
fexofenadine HCl USP, 60 mg	Antihistamine

**Uses** Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ itchy, watery eyes ■ sneezing ■ 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, call your doctor or contact a Poison Control Center right away (1-800-222-1222).

**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** ■ store between 20° and 25°C (68° to 77°F) ■ protect from excessive moisture ■ each tablet contains sodium 2.7 mg ■ this product meets the requirements of USP Dissolution Test 2

**Inactive ingredients** anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide

**Questions or comments?** Call toll-free 1-888-588-1418 Monday-Friday 9AM-7PM EST

\*This product is not manufactured or distributed by Chantem, Inc., a Sanofi Company, distributor of Allegra® Allergy

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Rev. 07/24 M-174  
PE-order No. 701295

**1.0" x 1.3"**  
**NO VARNISH**



0904719240 3

**MAJOR®**

**NDC 0904-7486-02**

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

**Non-Drowsy**

**Fexofenadine Hydrochloride Tablets, USP**

**180 mg**

**Antihistamine**

**24-Hour**

**Indoor/Outdoor Allergy Relief**

■ Sneezing ■ Runny Nose

■ Itchy, Watery Eyes ■ Itchy Nose or Throat

30 Tablets

Allergy Relief

**MAJOR**<sup>®</sup>

NDC 0904-7486-02

Compare to the active ingredient in Allegra<sup>®</sup> Allergy 24 Hour Tablets\*

Non-Drowsy

**Fexofenadine Hydrochloride Tablets, USP**

**180 mg**

Antihistamine

24-Hour Indoor/Outdoor Allergy Relief

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

**30 Tablets**

**Allergy Relief**

**TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDERCAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING**

<b>Drug Facts</b>
<b>Active ingredient (in each film-coated tablet)</b> Fexofenadine HCl USP, 180 mg
<b>Purpose</b> Antihistamine
<b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ itchy, watery eyes ■ sneezing ■ itching of the nose or throat
<b>Warnings</b> Do not use if you have ever had an allergic reaction to this product or any of its ingredients.
<b>Ask a doctor before use if you have</b> kidney disease. Your doctor should determine if you need a different dose.
<b>When using this product</b>
<ul style="list-style-type: none"> <li>■ do not take more than directed</li> <li>■ do not take at the same time as aluminum or magnesium antacids</li> <li>■ do not take with fruit juices (see Directions) ▶</li> </ul>

(Continued On Back Of Label)  
\*This product is not manufactured or distributed by Chatham, Inc., a Sanofi Company, distributor of Allegra<sup>®</sup> Allergy 24 Hour.

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Rev. 07/24 M-174 Re-order No. 701397



**NO VARNISH 0.3" x 1.2"**

**ADHESIVE AREA**

**Questions or comments?** Call toll-free 1-888-588-1418 Monday-Friday 9AM-7PM EST

**Inactive ingredients:** anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide

**Other information**  
■ store between 20° and 25°C (68° to 77°F) ■ protect from excessive moisture ■ each tablet contains: sodium 8.2 mg ■ this product meets the requirements of USP Dissolution Test 2

**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

**Drug Facts (continued)**

**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).

**ADHESIVE AREA**

**MAJOR**<sup>®</sup>

**NDC 0904-7486-60**

Compare to the active ingredient in Allegra<sup>®</sup> Allergy 24 Hour Tablets \*

**Non-Drowsy**

**Fexofenadine Hydrochloride Tablets, USP**

**180 mg**

**Antihistamine**

**24-Hour**

**Indoor/Outdoor Allergy Relief**

■ Sneezing ■ Runny Nose

■ Itchy, Watery Eyes ■ Itchy Nose or Throat

**100 Tablets**

# Allergy Relief

<p><b>MAJOR</b><sup>®</sup> NDC 0904-7486-60 Compare to the active ingredient in Allegra<sup>®</sup> Allergy 24 Hour Tablets*</p> <p><b>Non-Drowsy</b> <b>Fexofenadine Hydrochloride Tablets, USP</b></p> <p><b>180 mg</b></p> <p><b>Antihistamine</b> 24-Hour Indoor/Outdoor Allergy Relief</p> <ul style="list-style-type: none"> <li>• Sneezing • Runny Nose</li> <li>• Itchy, Watery Eyes • Itchy Nose or Throat</li> </ul> <p><b>100 Tablets</b>      <b>Allergy Relief</b></p>		<p><b>TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDERCAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING</b></p>	
<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each film-coated tablet)</b> Fexofenadine HCl USP, 180 mg</p> <p><b>Purpose</b> Antihistamine</p> <p><b>Uses</b> Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <input type="checkbox"/> runny nose <input type="checkbox"/> itchy, watery eyes <input type="checkbox"/> sneezing <input type="checkbox"/> itching of the nose or throat</p> <p><b>Warnings</b> Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p><b>Ask a doctor before use if you have</b> kidney disease. Your doctor should determine if you need a different dose.</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>do not take more than directed</li> <li>do not take at the same time as aluminum or magnesium antacids</li> <li>do not take with fruit juices (see Directions)</li> </ul>		<p>(Continued On Back Of Label) *This product is not manufactured or distributed by Chatham, Inc., a Sanofi Company, distributor of Allegra<sup>®</sup> Allergy 24 Hour. Distributed by: MAJOR<sup>®</sup> PHARMACEUTICALS Indianapolis, IN 46268 (800) 616-2471 www.majorpharmaceuticals.com Rev. 07/24 M-174 Re-order No. 701399</p>	
<p><b>ADHESIVE AREA</b></p>		<p><b>ADHESIVE AREA</b></p>	

<p><b>ADHESIVE AREA</b></p>		<p><b>ADHESIVE AREA</b></p>	
<p><b>Questions or comments?</b> Call toll-free 1-888-588-1418 Monday-Friday 9AM-7PM EST</p>		<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if</b> an allergic reaction to this product occurs. Seek medical help right away.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p><b>Directions</b> <input type="checkbox"/> 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</p> <p><input type="checkbox"/> children under 12 years of age do not use <input type="checkbox"/> adults 65 years of age and older ask a doctor <input type="checkbox"/> consumers with kidney disease ask a doctor</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store between 20° and 25°C (68° to 77°F)</li> <li>protect from excessive moisture</li> <li>each tablet contains: sodium 8.2 mg</li> <li>this product meets the requirements of USP Dissolution Test 2</li> </ul> <p><b>Inactive ingredients</b> anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide</p>	

**MAJOR**<sup>®</sup>

**NDC 0904-7486-40**

Compare to the active ingredient in Allegra<sup>®</sup> Allergy 24 Hour Tablets\*

**Non-Drowsy**

**Fexofenadine Hydrochloride Tablets, USP**

**180 mg**

**Antihistamine**

**24-Hour**

**Indoor/Outdoor Allergy Relief**

■ Sneezing ■ Runny Nose  
 ■ Itchy, Watery Eyes ■ Itchy Nose or Throat  
 500 Tablets  
 Allergy Relief

**MAJOR<sup>®</sup>** NDC 0904-7486-40  
 Compare to the active ingredient in Allegra<sup>®</sup> Allergy 24 Hour Tablets\*

**Non-Drowsy**  
**Fexofenadine Hydrochloride Tablets, USP**

**180 mg**

**Antihistamine**  
 24-Hour  
**Indoor/Outdoor Allergy Relief**

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

**500 Tablets**    **Allergy Relief**

**TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDERCAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING**

**Drug Facts**

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

**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 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*

**Inactive ingredients** anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregeatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide.

**Questions or comments?** Call toll-free 1-888-588-1418 Monday-Friday 9AM-7PM EST

**1.0" x 1.3"**  
NO VARNISH



\*This product is not manufactured or distributed by Chatham, Inc., a Sanofi Company, distributor of Allegra<sup>®</sup> Allergy 24 Hour.  
 MAJOR PHARMACEUTICALS Indianapolis, IN 46286  
 (800) 616-2471 www.majorpharmaceutical.com  
 Rev 07/24 M-174 R4-order No. 21160

## FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-7192
<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>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

### Product Characteristics

Color	pink	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	SG;201
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7192-04	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2024	
2	NDC:0904-7192-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/26/2021	
3	NDC:0904-7192-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/26/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	08/26/2021	

## FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7486
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)	

<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	

<b>Product Characteristics</b>			
<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	SG;202
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7486-02	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2024	
2	NDC:0904-7486-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2024	
3	NDC:0904-7486-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2024	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	08/20/2024	

**Labeler** - Major Pharmaceuticals (191427277)

**Registrant** - ScieGen Pharmaceuticals, Inc. (079391286)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
ScieGen Pharmaceuticals, Inc.		079391286	analysis(0904-7192, 0904-7486) , manufacture(0904-7192, 0904-7486) , pack(0904-7192, 0904-7486) , label(0904-7192, 0904-7486)