

**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

**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 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

## Other information

- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture
- **each tablet contains:** sodium 2.7mg(for 60 mg)
- this product meets the requirements of USP *Dissolution Test 2*

## Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch(maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide titanium dioxide and yellow iron oxide.

## Questions or comments?

Call toll-free **1-800-616-2471**

Distributed by:

**MAJOR<sup>®</sup> PHARMACEUTICALS**

Livonia, MI 48152

## Package/Label Principal Display Panel

**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 HR**

# Indoor/Outdoor Allergy Relief

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

**100 Tablets Allergy**

**MAJOR®** NDC 0904-7192-60  
Compare to the active ingredient in Allegra® Allergy\*

**Non-Drowsy**  
**Fexofenadine Hydrochloride Tablets USP**  
**60 mg**  
**Antihistamine**  
12 HR  
Indoor/Outdoor Allergy Relief

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

**100 Tablets Allergy**

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

Drug Facts	Purpose
<b>Active Ingredient</b> (in each film-coated tablet) Fexofenadine HCl USP, 60 mg	Antihistamine
<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
<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 Chatterm, Inc., a Sanofi Company, distributor of Allegra® Allergy

Distributed by: **MAJOR® PHARMACEUTICALS**  
Livonia, MI 48152

Rev. 08/21 M-174 Re-order No. 701294

3 09047 19260 1

LOT

EXP

PEEL HERE →

4.5" L
1.0"

**ADHESIVE AREA**

**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).

**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**

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- 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, lactose monohydrate, pregelatinized starch (maize), stearic acid, opadry pink 03B84993 containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide and yellow iron oxide

**Questions? Call 1-800-616-2471**

**ADHESIVE AREA**

**MAJOR®**

**NDC 0904-7192-40**

Compare to the active ingredient in Allegra® Allergy \*

**Non-Drowsy**

**Fexofenadine Hydrochloride Tablets USP**

**60 mg**

**Antihistamine**



**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

**FERRIC OXIDE YELLOW** (UNII: EX438O2MRT)

### Product Characteristics

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

### Packaging

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

**Labeler** - Major Pharmaceuticals (191427277)

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

### Establishment

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

Revised: 9/2021

Major Pharmaceuticals