

FEXOFENADINE HCL- fexofenadine hcl tablet, film coated
Major Pharmaceuticals

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[®]

NDC 0904-7192-04

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

100 Tablets

Allergy Relief

MAJOR[®]

NDC 0904-7192-04

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

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[®] Allergy

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Indianapolis, IN 46268
(800) 616-2471 www.majorpharmaceuticals.com

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

■ 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

Other Information

■ **ask a doctor** ■ **consumers with kidney disease**

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

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[®]

NDC 0904-7192-60

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

100 Tablets
Allergy Relief

MAJOR®	NDC 0904-7192-60	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		
100 Tablets	Allergy Relief	
TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDERCAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING		
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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) ▶		
<small>(Continued On Back Of Label)</small> *This product is not manufactured or distributed by Chatterm, Inc, a Sanofi Company, distributor of Allegra® Allergy Distributed by: MAJOR® PHARMACEUTICALS Indianapolis, IN 46268 (800) 616-2471 www.majorpharmaceuticals.com Rev. 07/24 M-174 Re-order No. 701294		
		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 2.7 mg ■ this product meets the requirements of USP Dissolution Test 2	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	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).	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
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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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MAJOR PHARMACEUTICALS
Indianapolis, IN 46268
(800) 616-5471
www.majorpharmaceuticals.com
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[®]

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

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, 180 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
<ul style="list-style-type: none"> ■ 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 Chatham, Inc., a Sanofi Company, distributor of Allegra[®] Allergy 24 Hour.

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(800) 616-2471 www.majorpharmaceuticals.com
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[®]

NDC 0904-7486-03

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

<p>MAJOR[®] NDC 0904-7486-03</p> <p>Compare to the active ingredient in Allegra[®] Allergy 24 Hour Tablets*</p> <p>Non-Drowsy</p> <p>Fexofenadine Hydrochloride Tablets, USP</p> <p>180 mg</p> <p>Antihistamine</p> <p>24-Hour</p> <p>Indoor/Outdoor Allergy Relief</p> <ul style="list-style-type: none"> • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Nose or Throat <p>30 Tablets Allergy Relief</p> <p><small>TAMPER EVIDENT: DO NOT USE IF FOL SEAL UNDERCAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING</small></p>	<table border="1"> <tr> <th>Drug Facts</th> </tr> <tr> <td> <p>Active ingredient (in each film-coated tablet) Fexofenadine HCl USP, 180 mg Antihistamine</p> <p>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</p> <p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ 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) ▶ </td> </tr> </table>	Drug Facts	<p>Active ingredient (in each film-coated tablet) Fexofenadine HCl USP, 180 mg Antihistamine</p> <p>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</p> <p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ 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) ▶ 	<p><small>(Continued On Back Of Label)</small></p> <p>*This product is not manufactured or distributed by Chatham, Inc., a Sanofi Company, distributor of Allegra[®] Allergy 24 Hour.</p> <p>Distributed by: MAJOR[®] PHARMACEUTICALS Indianapolis, IN 46268 (800) 616-2471 • www.majorpharmaceuticals.com Rev. 07/24 M-174 Re-order No. 701398</p>  <p>3 0904748603 8</p> <p>NO VARNISH 0.3" x 1.2"</p> <p>TEAR HERE</p>
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MAJOR[®]

NDC 0904-7486-60

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
100 Tablets
Allergy Relief

MAJOR[®] NDC 0904-7486-60 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 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, 180 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)
(Continued On Back Of Label) *This product is not manufactured or distributed by Chattem, Inc., a Sanofi Company, distributor of Allegra [®] Allergy 24 Hour. Distributed by: MAJOR [®] PHARMACEUTICALS Indianapolis, IN 46268 (800) 616-2471 www.majorpharmaceuticals.com Rev. 07/24 M-174 Re-order No. 701399		

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	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 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
ADHESIVE AREA	

MAJOR[®]
NDC 0904-7486-40
 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

500 Tablets

Allergy Relief

MAJOR[®]

NDC 0904-7486-40

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

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
<p>Active Ingredient (in each film-coated tablet) Purpose Fexofenadine HCl USP, 180 mg Antihistamine</p> <p>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</p> <p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.</p> <p>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)</p> <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>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).</p> <p>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</p> <p>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 <i>Dissolution Test 2</i></p> <p>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.</p> <p>Questions or comments? Call toll-free 1-888-588-1418 Monday-Friday 9AM-7PM EST</p>

*This product is not manufactured or distributed by Chatham, Inc., a Sanofi Company, distributor of Allegra[®] Allergy 24 Hour.

MAJOR PHARMACEUTICALS Indianapolis, IN 46286
(800) 616-2671 www.majorpharmaceutical.com
Rev. 07/24 M-174 R4-order No. 2160

1.0" x 1.3"
NO VARNISH

N 3 0904748640 3

FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7192
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (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
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ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	SG;202
Contains			

Packaging

#	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:0904-7486-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2024	
3	NDC:0904-7486-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2024	
4	NDC:0904-7486-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2024	

Marketing Information

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)

Establishment

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)

