

FEXOFENADINE HCL- fexofenadine hcl tablet, film coated
Radha 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.

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 **1-855-724-3436**

Distributed by: **Radha Pharmaceuticals Inc**

Hauppauge, NY 11788 USA

Package/Label Principal Display Panel

Radha Pharmaceuticals Inc

NDC 77771-201-01

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

<p style="font-size: small;">NDC 77771-201-01 Compare to the active ingredient in Allegra® Allergy*</p> <p style="text-align: center;">ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY</p> <div style="background-color: #0070C0; color: white; padding: 5px; text-align: center;"> <p>Fexofenadine Hydrochloride Tablets, USP 60 mg/antihistamine</p> </div> <p style="text-align: center;">Allergy Indoor and Outdoor Allergies 12 Hour Relief of ■ Sneezing ■ Runny Nose ■ Itchy, Watery Eyes ■ Itchy Nose or Throat</p> <p>100 Tablets 60 mg each</p> <p style="text-align: center;"> Radha Pharmaceuticals Inc.</p>	<p>Drug Facts</p> <p>Active ingredient (in each film-coated tablet) Fexofenadine HCl USP, 60 mg..... Antihistamine</p> <p>Purpose 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>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 style="font-size: x-small;">*This product is not manufactured or distributed by Chattem, Inc., a Sanofi Company, distributor of Allegra® Allergy.</p>	<p style="text-align: right;">SEE BACK</p> <div style="border: 2px solid orange; padding: 5px;"> <p style="text-align: center; color: orange; font-weight: bold;">NO VARNISH 0.3" x 1.2"</p> </div> <p style="text-align: center;">3 77771 20101 2</p> <p style="font-size: x-small;">Distributed by: Radha Pharmaceuticals, Inc. Hauppauge, NY 11788 USA Rev. 03/25</p>
<p style="color: orange; font-weight: bold; font-size: 2em;">ADHESIVE AREA</p>	<p>Drug Facts (Continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>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</p> <p>Other information ■ store between 20° and 25°C (68° and 77°F) ■ protect from excessive moisture ■ each tablet contains: sodium 2.7 mg ■ this product meets the requirements of USP Dissolution Test 2</p> <p>■ Tamper Evident: Do not use if imprinted inner safety seal is torn or missing.</p> <p>Inactive ingredients anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch (maize), stearic acid, and coating agent containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide and yellow iron oxide.</p> <p>Questions or comments? call toll-free 1-855-724-3436</p>	<p style="color: orange; font-weight: bold; font-size: 2em;">ADHESIVE AREA</p>

Radha Pharmaceuticals Inc
NDC 77771-201-05

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

NDC 77771-201-05 ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY	
Compare to the active ingredient in Allegra® Allergy*	
Fexofenadine Hydrochloride Tablets, USP 60 mg/antihistamine	
Allergy Indoor and Outdoor Allergies 12 Hour Relief of ▪ Sneezing ▪ Runny Nose ▪ Itchy, Watery Eyes ▪ Itchy Nose or Throat	
500 Tablets	60 mg each
	
Drug Facts	Active Ingredient (in each film-coated tablet)
Fexofenadine HCl USP 60 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. Seek medical help right away.	
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 ■ store between 20° and 25°C (68° and 77°F) ■ protect from excessive moisture ■ each tablet contains: sodium 2.7 mg ■ this product meets the requirements of USP Dissolution Test 2 ■ Tamper Evident: Do not use if imprinted inner safety seal is torn or missing.	
Inactive ingredients antihydroxy lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch (maize), stearic acid, and coating agent containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide and yellow iron oxide.	
Questions or comments? call toll-free 1-855-724-3436	
*This product is not manufactured or distributed by Chatterm, Inc., a Sanofi Company, distributor of Allegra® Allergy.	
Distributed by: Radha Pharmaceuticals, Inc. Hempstead, NY 11798 USA Rev: 03/25	
LOT: EXP:	
NO VARNISH 1.0561 in x 1.1 in	
 N 3 77771-201-05 0	

Radha Pharmaceuticals Inc

NDC 77771-202-30

Compare to the active ingredient in Allegra® Allergy*

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>NDC 77771-202-30 ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY</p> <p>Flexfenadine Hydrochloride Tablets, USP 180 mg/antihistamine</p> <p>Allergy Indoor and Outdoor Allergies 24 hour Relief of ■ Sneezing ■ Runny Nose ■ Itchy, Watery Eyes ■ Itchy Nose or Throat</p> <p>30 Tablets 180 mg each</p> 		<p>Compare to the active ingredient in Allegra® Allergy 24 Hour Tablets*</p> <p>Drug Facts</p> <p>Active ingredient (in each film-coated tablet) Flexfenadine HCl USP, 180 mg..... Antihistamine</p> <p>Purpose 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><small>*This product is not manufactured or distributed by Chatten, Inc., a Sanofi Company, distributor of Allegra® Allergy 24 Hour.</small></p> <p>Distributed by: Radha Pharmaceuticals, Inc. Hauptpauge, NY 11788 USA Rev. 03/25</p>  <p>3 7777120230 9</p> <p>NO VARNISH 0.3" x 1.2"</p> <p style="text-align: right;">↑ 30 TABLETS</p>	
<p>ADHESIVE AREA</p>		<p>ADHESIVE AREA</p>	
<p>Questions or comments? call toll-free 1-855-724-3436</p>		<p>Drug Facts (Continued)</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.</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 Dissolution Test 2</p> <p>■ Tamper Evident: Do not use if imprinted inner safety seal is torn or missing.</p> <p>Inactive ingredients anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch (maize), stearic acid, and coating agent containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide and yellow iron oxide.</p>	

Radha Pharmaceuticals Inc

NDC 77771-202-01

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

Non-Drowsy

**Flexfenadine 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>NDC 77771-202-01 Compare to the active ingredient in Allegra® Allergy 24 Hour Tablets*</p> <p>ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY</p> <p>Flexofenadine Hydrochloride Tablets, USP 180 mg/antihistamine</p> <p>Allergy Indoor and Outdoor Allergies 24 hour Relief of ■ Sneezing ■ Runny Nose ■ Itchy, Watery Eyes ■ Itchy Nose or Throat</p> <p>100 Tablets 180 mg each</p> <p> Radha Pharmaceuticals Inc.</p>		<p>Drug Facts</p> <p>Active ingredient (in each film-coated tablet) Flexofenadine HCl USP, 180 mg..... Antihistamine</p> <p>Purpose 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><small>*This product is not manufactured or distributed by Chattem, Inc., a Sanofi Company, distributor of Allegra® Allergy 24 Hour.</small></p> <p>Distributed by: Radha Pharmaceuticals, Inc. Hauppauge, NY 11788 USA Rev. 03/25</p> <p> N 3 7777120201 9</p> <p>NO VARNISH 0.3" x 1.2"</p> <p>PEEL HERE </p>	
<p>ADHESIVE AREA</p> <p>Drug Facts (Continued)</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.</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> ■ Tamper Evident: Do not use if imprinted inner safety seal is torn or missing.</p> <p>Inactive ingredients anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch (maize), stearic acid, and coating agent containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide and yellow iron oxide.</p> <p>Questions or comments? call toll-free 1-855-724-3436</p>		<p>ADHESIVE AREA</p>	

Radha Pharmaceuticals Inc

NDC 77771-202-05

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

Non-Drowsy

Flexofenadine 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

NDC 77771-202-05
ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

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

Fexofenadine Hydrochloride

Tablets, USP

180 mg/antihistamine

Allergy
Indoor and Outdoor Allergies
24 hour Relief of

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

500 Tablets 180 mg each

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
- 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 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*
■ Tamper Evident: Do not use if imprinted inner safety seal is torn or missing.

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

Questions or comments? call toll-free 1-855-724-3458

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

NO VARNISH

1.0561 in x 1.5248 in

LOT:
EXP

N 777712020517

FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77771-201
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: 3S5Y5LH9PMK)	
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:77771-201-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2025	
2	NDC:77771-201-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA204507	03/10/2025		

FEXOFENADINE HCL			
fexofenadine hcl tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77771-202
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)			
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:77771-202-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2025	
2	NDC:77771-202-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2025	
3	NDC:77771-202-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	03/10/2025	

Labeler - Radha Pharmaceuticals (117634222)

Registrant - ScieGen Pharmaceuticals, Inc. (079391286)

Establishment

Name	Address	ID/FEI	Business Operations
ScieGen Pharmaceuticals, Inc.		079391286	analysis(77771-201, 77771-202) , manufacture(77771-201, 77771-202) , pack(77771-201, 77771-202) , label(77771-201, 77771-202)

Revised: 3/2025

Radha Pharmaceuticals