

**FEXOFENADINE HYDROCHLORIDE- fexofenadine hcl tablet**  
**Major Pharmaceuticals**

-----  
**Major Pharmaceuticals**

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

Fexofenadine HCL 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**

- 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 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

- **each tablet contain:** sodium 8 mg
- store between 20 to 25°C (68 to 77°F)
- protect from excessive moisture
- 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: **1-800-616-2471**

## Principal Display Panel

COMPARE TO the active ingredient in ALLEGRA® ALLERGY 24 HOUR\*

## **FEXOFENADINE HYDROCHLORIDE USP 180 mg**

### **Antihistamine**

ALLERGY RELIEF

24-HOUR Relief of:

- sneezing
- Runny nose
- Itchy, watery eyes
- Itchy nose or throat

Indoor and Outdoor

Allergy Relief

Non-Drowsy

Capsule Shaped Tablets

\*This product is not manufactured or distributed by Chattem Inc., distributor of Allegra® Allergy 24 hour

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Distributed by:

**MAJOR® PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

**Product Label**

**MAJOR®** NDC 0904-7050-40  
COMPARE TO the active ingredient in ALLEGRA® ALLERGY 24 HOUR\*

**FEXOFENADINE HYDROCHLORIDE USP, 180 mg**  
Antihistamine

**ALLERGY RELIEF**

24-Hour Relief of:

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

Indoor and Outdoor Allergy Relief

Non-Drowsy

**500**  
Capsule Shaped Tablets

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

<b>Drug Facts</b>	<b>Purpose</b> Antihistamine
<b>Active ingredient (in each film-coated tablet)</b> Fexofenadine HCl USP 180 mg	
<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. Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose. <b>When using this product:</b> ■ 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)	
<b>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).</b>	
<b>Directions</b> 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	
<b>Other information</b> ■ each tablet contains: sodium 8 mg ■ store between 20-25°C (68-77°F) ■ protect from excessive moisture ■ this product meets the requirements of USP Dissolution Test 2	
<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	
<b>Questions or comments?</b> Call 1-800-616-2471	

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

Distributed by:  
**MAJOR PHARMACEUTICALS**  
17177 N Laurel Park Drive, Suite 233  
Livonia, MI 48152

Rev. 01/20 M-58 Re-order No. 701277

3 09047-05040 6

Exp. Date: \_\_\_\_\_

Lot No.: \_\_\_\_\_

PLD-B4168  
LB007546

**MAJOR PHARMACEUTICALS Allergy Relief**

<b>FEXOFENADINE HYDROCHLORIDE</b>			
fexofenadine hcl tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-7050
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	<b>FEXOFENADINE HYDROCHLORIDE</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<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>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7050-40	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2019	10/28/2026
2	NDC:0904-7050-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2019	10/28/2026

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	11/29/2019	10/28/2026

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 7/2025

Major Pharmaceuticals