

FEXOFENADINE HYDROCHLORIDE- fexofenadine hcl tablet
Major Pharmaceuticals

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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.

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: ■ 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).
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Questions or comments? Call 1-800-616-2471

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

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Exp. Date:

Lot No.:

PLD-B4188
LB007546

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

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MAJOR PHARMACEUTICALS Allergy Relief

FEXOFENADINE HYDROCHLORIDE

fexofenadine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7050
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:0904-7050-40	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2019	
2	NDC:0904-7050-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2019	

Marketing Information

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

Labeler - Major Pharmaceuticals (191427277)

Revised: 12/2022

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