

ALLERGY RELIEF- fexofenadine hcl tablet, coated
Major Pharmaceuticals

DRUG FACTS

Active ingredient (in each 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).

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
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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

- safety sealed: do not use if printed safety seal under cap is missing or broken
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide, 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 0904-6978-60
 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

Actual Size

100
Capsule Shaped Tablets



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

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Active ingredient (in each 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.	

Drug Facts (continued under label)

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

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

Rev. 09/19 M-58 Re-order No. 701205



PLD-A490A
 LB007162

Lot No.:
 Exp. Date:

PEEL HERE →

Drug Facts (continued)	
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) 	
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

MAJOR PHARMACEUTICAL Allergy Relief

ALLERGY RELIEF

fexofenadine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6978
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	PINK	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	J;44
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6978-40	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/23/2019	11/30/2021
2	NDC:0904-6978-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/23/2019	11/30/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204097	09/23/2019	11/30/2021

Labeler - Major Pharmaceuticals (191427277)

Revised: 10/2020

Major Pharmaceuticals