

ALLERGY RELIEF- fexofenadine hcl tablet, coated
Medstone Pharma LLC

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 18 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

- safety sealed: do not use if printed safety seal under cap is missing or broken or if individual blister units are torn or opened
- 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 **1-877-753-3935**

Principal Display Panel

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

Allergy Relief

Fexofenadine HCL USP

Antihistamine

Caplets**

(**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:

Medstone Pharma LLC

3300 Corporate Ave. #112

Weston, FL 33331

Product Label

NDC 71626-502-05
*Compare to the active ingredient in Allegra® Allergy 24 Hour



Allergy Relief

Fexofenadine HCl USP

Antihistamine

180 mg

500 Caplets**
(* **Capsule-Shaped Tablets)

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

Drug Facts		
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: <ul style="list-style-type: none"> ■ 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 <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).	
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 one 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	<ul style="list-style-type: none"> ■ Tamper evident: do not use if printed safety seal under cap is missing or broken or if individual blister units are torn ■ 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 1-877-753-3935	

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Distributed by:
Medstone Pharma LLC
 3300 Corporate Ave. #112
 Weston, FL 33331



Rev. 07/19
 PLD-A490A
 LB007031
 Lot No.:
 Exp. Date:
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MEDSTONE PHARMA Allergy Relief

ALLERGY RELIEF

fexofenadine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71626-502
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)	
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:71626-502-05	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2019	01/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204097	10/01/2019	01/31/2025

Labeler - Medstone Pharma LLC (080783388)