

ALLERGY RELIEF- fexofenadine hcl tablet, coated
PLD Acquisitions LLC DBA Avéma Pharma Solutions

DRUG FACTS

Active ingredient (in each tablet)

Fexofenadine HCl USP 60 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 (1-

800-222-1222).

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

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

Inactive ingredients

colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide, and yellow iron oxide

Questions or comments?

Principal Display Panel

*Compare to the active ingredient in Allegra® Allergy 12 hour

Allergy Relief

Fexofenadine HCL USP 180 mg

Antihistamine

12 HOUR RELIEF OF:

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

Caplets**

(**Capsule-shaped Tablets)

*This product is not manufactured or distributed by Chattem, Inc., distributor of Allegra® Allergy 12 hour.

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

Product Label

NDC 63548-0663-5

*Compare to the active ingredient in Allegra® Allergy 12 Hour

Allergy Relief

Flexofenadine HCl USP 60 mg Antihistamine

- 12-hour relief of
- ✓ Sneezing
 - ✓ Runny nose
 - ✓ Itchy, watery eyes
 - ✓ Itchy nose or throat

Indoor and outdoor allergy relief
Non-drowsy

500 Caplets**
(**Capsule-shaped tablets)



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

Drug Facts	Purpose
Active ingredient (in each tablet) Flexofenadine 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. 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). (optional)	

Drug Facts (continued under label)

*This product is not manufactured or distributed by Chattem, Inc., distributor of Allegra® Allergy 12 Hour.

Distributed by:
(Specific to customer's labeling guide.
Must state either: manufacturer, packer,
or distributor)



PLD-A505A L6000000
Lot No.:
Exp. Date:



Drug Facts (continued)	
Directions	take one 60 mg tablet with water every 12 hours. do not take more than 2 tablets in 24 hours
adults and children 12 years of age and over	
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	
■ Tamper Evident: do not use if printed safety seal under cap is broken or missing	
■ store between 20° and 25°C (68° and 77°F)	
■ protect from excessive moisture	
Inactive ingredients colloidal silicon dioxide, hypromellose, light liquid paraffin, 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-XXX-XXX-XXXX DMS & TIMES & ZONE (specific to customer's labeling guide)	

Allergy Relief

ALLERGY RELIEF
fexofenadine hcl tablet, coated

Product Information	
Product Type	HUMAN OTC DRUG
Route of Administration	ORAL
Item Code (Source)	NDC:63548-0663

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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, CORN (UNII: O8232NY3SJ)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics			
Color	pink	Score	no score
Shape	CAPSULE	Size	12mm
Flavor		Imprint Code	J;43
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63548-0663-5	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2019	

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

Labeler - PLD Acquisitions LLC DBA Avéma Pharma Solutions (804087794)