

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

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**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

**Fexofenadine 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)



Actual Size

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 tablet)</b> Fexofenadine HCl USP 60 mg	
<b>Uses</b> 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	
<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.</b> Seek medical help right away. <b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b> 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 Chatterm, Inc., distributor of Allegra® Allergy 12 Hour.

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



Lot No.:  
Exp. Date:

PLD-4605A LB000000



<b>Drug Facts (continued)</b>	
<b>Directions</b>	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	ask a doctor
children under 12 years of age	ask a doctor
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor
<b>Other information</b>	■ 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
<b>Inactive ingredients</b>	colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, poly(sorbate 80), pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide, yellow iron oxide
<b>Questions or comments? Call 1-XXX-XXX-XXXX DAVIS &amp; SONNE (specific to customer's labeling guide)</b>	

## Allergy Relief

### ALLERGY RELIEF

fexofenadine hcl tablet, coated

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63548-0663
<b>Route of Administration</b>	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXO FENADINE HYDRO CHLORIDE (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)