# 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 HCI 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-

#### **Directions**

	take one 60 mg tablet with water every 12 hours; do not take more than 2 tablets in 24 hours
	do not use
age	
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

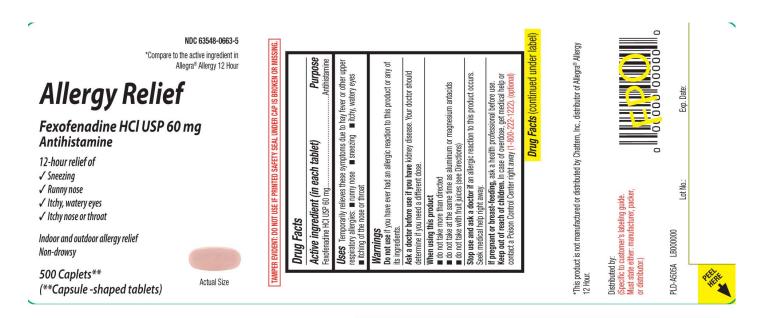
Caplets\*\*

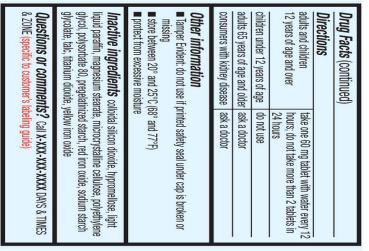
(\*\*Capsule-shaped Tablets)

\*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**





**Allergy Relief** 

ALLERGY RELIEF				
fexofenadine hcl tablet, coated				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63548-0663	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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: EX43802MRT)				
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				

F	Packaging				
#	tem 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)