

**ALLEGRA-D ALLERGY AND CONGESTION- fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release  
Chattem, Inc.**

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**Allegra-D Allergy and Congestion 12 HR**

***Drug Facts***

***Active ingredients***

***(in each tablet)***

Fexofenadine HCl 60 mg

***Purpose***

Antihistamine

***Active ingredients***

***(in each tablet)***

Pseudoephedrine HCl 120 mg

***Purpose***

Nasal decongestant

***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
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

***Warnings***

***Do not use***

- if you have ever had an allergic reaction to this product or any of its ingredients

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- If you have difficulty swallowing

**Ask a doctor before use if you have**

- heart disease
- thyroid disease
- glaucoma
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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)
- the tablet coating may be seen in the stool (this is normal). Continue to take as directed (see Directions).

**Stop use and ask a doctor if**

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve within 7 days or are accompanied by a fever
- you get nervous, dizzy, or sleepless

**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.

**Directions**

- do not divide, crush, chew or dissolve the tablet; swallow tablet whole

adults and children 12 years of age and over	take 1 tablet with a glass of water every 12 hours on an empty stomach; do not take more than 2 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 carton is opened or if individual blister units are torn or opened
- store between 20° and 25°C (68° and 77°F)

### ***Inactive ingredients***

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, stearic acid

### ***Questions or comments?***

call toll-free **1-800-633-1610** or [www.allegra.com](http://www.allegra.com)

### **PRINCIPAL DISPLAY PANEL**

NDC 41167-4310-6

Allegra-D®

Allergy &

Congestion 12HR

fexofenadine HCl 60 mg/antihistamine

pseudoephedrine HCl 120 mg/nasal decongestant

Extended Release Tablets

30 Tablets



## ALLEGRA-D ALLERGY AND CONGESTION

fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41167-4310
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FEXOFENADINE HYDROCHLORIDE</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

## Product Characteristics

<b>Color</b>	white (white and tan)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	06;012D
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-4310-2	1 in 1 CARTON	03/03/2011	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41167-4310-4	2 in 1 CARTON	03/03/2011	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41167-4310-6	3 in 1 CARTON	03/03/2011	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020786	03/03/2011	

