**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 20º and 25ºC (68º and 77ºF)

### *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

### 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 | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:41167-4310 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **FEXOFENADINE HYDROCHLORIDE** (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V) | FEXOFENADINE HYDROCHLORIDE | 60 mg |
| **PSEUDOEPHEDRINE HYDROCHLORIDE** (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 120 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white (white and tan) | **Score** | no score |
| **Shape** | OVAL | **Size** | 19mm |
| **Flavor** | | **Imprint Code** | 06;012D |
| **Contains** | | | |

## 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 | |

**Labeler -** Chattem, Inc. (003336013)

Revised: 1/2026 Chattem, Inc.