

ALLEGRA ALLERGY- fexofenadine hydrochloride tablet, coated
Chattem, Inc.

Allegra Allergy

Allegra Allergy® Gelcaps – 24 HOUR

Drug Facts

Active ingredient

(in each tablet)

Fexofenadine HCl 180 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, water 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.

Directions

| | |
|--|---|
| adults and children 12 years of age and over | take one 180 mg tablet with water once a day; do not take more than 1 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)
- protect from excessive moisture

Inactive ingredients

croscarmellose sodium, D&C red 28, D&C red 33, FD&C blue 1, gelatin, hydroxypropylcellulose, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, PEG-135, pharmaceutical ink, pregelatinized starch, titanium dioxide

Questions or comments?

call toll-free **1-800-633-1610** or www.allegra.com

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Dist. By: Chattem, Inc., a Sanofi Company, Chattanooga, TN 37409-0219 ©2014

PRINCIPAL DISPLAY PANEL

NDC 41167-4122-0

Allegra®

ALLERGY

fexofenadine HCl tablet

180 mg/antihistamine

24 HR

8 GELCAPS

Allegra
ALLERGY
24 HR

NDC 41167-4122-0

NON-DROWSY

8 GELCAPS

NON-DROWSY

Allegra
ALLERGY
fexofenadine HCl tablet
180 mg/antihistamine 24 HR

INDOOR / OUTDOOR ALLERGY RELIEF

- ✓ Sneezing
- ✓ Runny Nose
- ✓ Itchy, Watery Eyes
- ✓ Itchy Nose or Throat

8 GELCAPS
Gel Coated Tablets Actual Size



Allegra 
ALLERGY



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LOT
Exp

| Drug Facts (continued) | |
|---|--|
| Directions adults and children take one 180 mg tablet with water once a day; do not take more than 1 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 | |
| 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. | |
| Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • itchy, watery eyes • sneezing • itching of the nose or throat | |
| Active ingredient (in each tablet) Purpose Fexofenadine HCl 180 mg Antihistamine | |
| Drug Facts | |
| Other Information • safety sealed; do not use if carton is opened or if individual blisters are torn or opened • store between 20° and 25°C (68° and 77°F) • protect from excessive moisture Inactive ingredients ascorbic acid, croscarmellose sodium, D5C red 28, D5C red 33, FD&C blue 1, gelatin, hydroxypropylcellulose, hypromellose, methylcellulose, magnesium stearate, microcrystalline cellulose, PEG-135, phenacetolol, polyethylene glycol, pregelatinized starch, titanium dioxide | |
| Questions or comments? call toll-free 1-800-633-1610 or www.allegra.com | |

Allegra
ALLERGY
24 HR

ALLEGRA ALLERGY

fexofenadine hydrochloride tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41167-4122 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------|-----------------|
| FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V) | FEXOFENADINE HYDROCHLORIDE | 180 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| D&C RED NO. 28 (UNII: 767IP0Y5NH) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GELATIN (UNII: 2G86QN327L) | |
| HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OPIR32D61U) | |
| POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|-----------------------------------|---------------------|----------|
| Color | PURPLE (White band in the middle) | Score | no score |
| Shape | OVAL (Caplet) | Size | 20mm |
| Flavor | | Imprint Code | AG;AG |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:41167-4122-0 | 1 in 1 CARTON | 12/17/2014 | |
| 1 | | 8 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:41167-4122-2 | 1 in 1 CARTON | 12/17/2014 | |
| 2 | | 60 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:41167-4122-5 | 1 in 1 CARTON | 12/17/2014 | |
| 3 | | 24 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 4 | NDC:41167-4122-6 | 1 in 1 CARTON | 12/17/2014 | |
| 4 | | 32 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 5 | NDC:41167-4122-9 | 2 in 1 CARTON | 12/17/2014 | 06/23/2019 |

5 NDC:41167-4122-7 40 in 1 BOTTLE; Type 0: Not a Combination Product

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA020872 | 12/17/2014 | |

Labeler - Chattem, Inc. (003336013)

Revised: 12/2014

Chattem, Inc.