

CHILDRENS ALLEGRA ALLERGY- fexofenadine hydrochloride tablet, orally disintegrating
Chattem, Inc.

Childrens Allegra Allergy

Drug Facts

Active ingredient

(in each tablet)

Fexofenadine HCl 30 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

- place 1 tablet on tongue; tablet disintegrates, with or without water

| | |
|--|--|
| adults and children 12 years of age and over | take 2 tablets every 12 hours on an empty stomach; do not take more than 4 tablets in 24 hours |
| children 6 to under 12 years of age | take 1 tablet every 12 hours on an empty stomach; do not take more than 2 tablets in 24 hours |
| children under 6 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

- phenylketonurics: contains phenylalanine 3.8 mg per tablet
- 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)
- use tablet immediately after opening individual blister
- contains lactose

Inactive ingredients

aspartame, crospovidone, flavors, lactose monohydrate, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, povidone, silicon dioxide

Questions or comments?

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

Dist. By: Chattem, Inc, a Sanofi Company,

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PRINCIPAL DISPLAY PANEL

NDC 41167-4232-1

NON-DROWSY

Children's

Allegra®

Allergy

**fexofenadine HCl orally disintegrating
tablet 30 mg/antihistamine
Indoor and Outdoor Allergies
Orange Cream flavor
12 Orally Disintegrating Tablets**



PRINCIPAL DISPLAY PANEL

**NDC 41167-4232-6
NON-DROWSY
Children's
Allegra®
Allergy
fexofenadine HCl orally disintegrating
tablet 30 mg/antihistamine
Indoor and Outdoor Allergies
Orange Cream flavor
24 Orally Disintegrating Tablets**



CHILDRENS ALLEGRA ALLERGY

fexofenadine hydrochloride tablet, orally disintegrating

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41167-4232 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------|----------|
| FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V) | FEXOFENADINE HYDROCHLORIDE | 30 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ASPARTAME (UNII: Z0H242BBR1) | |
| CROSPROVIDONE (UNII: 2S7830E561) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POVIDONE (UNII: FZ989GH94E) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |

Product Characteristics

| | | | |
|-----------------|-----------------------|---------------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 11mm |
| Flavor | ORANGE (Orange Cream) | Imprint Code | e;311;AV |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:41167-4232-1 | 2 in 1 CARTON | 01/02/2014 | |
| 1 | | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:41167-4232-6 | 4 in 1 CARTON | 01/02/2014 | |
| 2 | | 6 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 | NDA021909 | 01/02/2014 | |

Labeler - Chattem, Inc. (003336013)

Revised: 8/2022

Chattem, Inc.