

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
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ASPARTAME (UNII: Z0H242BBR1)	
CROSPVIDONE (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	12/01/2024
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)