

**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
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	

CROSPVIDONE (UNII: 2S7830E561)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (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)