CHILDRENS ALLEGRA ALLERGY- fexofenadine hydrochloride suspension Chattem, Inc.

Childrens Allegra Allergy Oral Suspension

Drug Facts

Active ingredient

(in each 5 mL)

Fexofenadine HCI 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

shake well before using

use only with enclosed dosing cup

adults and children 12 years of age and over	take 10 mL every 12 hours; do not take more than 20 mL in 24 hours	
children 2 to under 12 years of age	take 5 mL every 12 hours; do not take more than 10 mL in 24 hours	
children under 2 years of age	ask a doctor	
adults 65 years of age and older	ask a doctor	
consumers with kidney disease	ask a doctor	

Note: mL = milliliters

Other information

• each 5 mL contains: sodium 18 mg

• safety sealed: do not use if carton is opened or if printed foil inner seal on bottle is torn or missing

store between 20° and 25°C (68° and 77°F)

Inactive ingredients

butylparaben, edetate disodium, flavor, poloxamer 407, propylene glycol, propylparaben, purified water, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, sucrose, titanium dioxide, xanthan gum, xylitol

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 41167-4244-4 Children's Allegra® ALLERGY fexofenadine HCI oral suspension 12 HR 30 mg/5 ml antihistamine



CHILDRENS ALLEGRA ALLERGY

fexofenadine hydrochloride suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-4244
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	FEXOFENADINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHO SPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70 WT22SF4B)	
SODIUM PHO SPHATE, MO NO BASIC, MO NO HYDRATE (UNII: 593YOG76RN)	
SUCROSE (UNII: C151H8 M554)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics		
Color	WHITE	Score
Shape		Size
Flavor	BERRY	Imprint Code
Contains		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41167-4244-4	1 in 1 CARTON	03/03/2011		
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:41167-4244-1	1 in 1 CARTON	03/03/2011		
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product			
3	NDC:41167-4244-7	3 in 1 CELLO PACK	03/03/2011		
3		120 mL 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	NDA201373	03/03/2011	

Labeler - Chattem, Inc. (003336013)

Revised: 3/2011 Chattem, Inc.