

Children's Allegra Allergy 4oz Oral Suspension
 ALG_K_12hr_4oz_FDA Submission 2

NON-DROWSY

Children's Allegra Allergy

Ages 2 Years & Older **12 Hour**

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Children's Allegra Allergy

Ages 2 Years & Older **12 Hour**

Drug Facts

Active ingredient Purpose
 (in each 5 mL teaspoonful)
 Fexofenadine HCl 30 mg Antihistamine

Uses
 temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 ■ runny nose ■ itchy, watery eyes
 ■ sneezing ■ 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 2 teaspoonfuls (10 mL) every 12 hours; do not take more than 4 teaspoonfuls (20 mL) in 24 hours
children 2 to under 12 years of age	take 1 teaspoonful (5 mL) every 12 hours; do not take more than 2 teaspoonfuls (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: teaspoonful = tsp

Other information
 ■ each 5 mL teaspoon 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

The makers of Allegra® do not make store brand products.
 The trade dress of this Allegra® package is subject to trademark protection.
 Dist. By: Chattem, Inc. (part of the sanofi-aventis Group), Chattanooga, TN 37409-0219 ©2012 5009SPA_UD-07

Indoor and Outdoor Allergies

Ages 2 Years & Older

12 Hour

Relief of:
 ✓ Runny Nose
 ✓ Sneezing
 ✓ Itchy, Watery Eyes
 ✓ Itchy Nose or Throat

Oral Suspension/ 4 fl. oz. (120ml)

alcohol free / dye free

berry FLAVOR

Dosing Cup Included
 Wash and let air dry after each use

alcohol free / dye free

berry FLAVOR

LOT

EXP

Title:
 14 point Helvetica Bold
 italic, left justified

Headings:
 8 point Helvetica Bold
 italic, left justified

Body Text:
 6 point Helvetica Regular
 left justified, 6.5 leading

Subheadings:
 6 point Helvetica Bold
 left justified

8 point Helvetica Regular

Title for Continued Panel:
 8 point Helvetica Bold Italic

Bullet:
 5 point
 solid square

2.5 point barline

table format for 3 or more doses

Graphic leading to next panel

Children's Allegra Allergy 4oz Oral Suspension

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Children's Allegra Allergy

Ages 2 Years & Older **12 Hour**

NON-DROWSY **NON-DROWSY** **NON-DROWSY**

NDC 41167-4244-4

Children's Allegra Allergy

Ages 2 Years & Older **12 Hour**

Drug Facts (continued)

Other information

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

Inactive ingredients

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Children's Allegra Allergy

fexofenadine HCl oral suspension
30 mg/5ml antihistamine

Indoor & Outdoor Allergies

Ages 2 Years & Older

12 Hour

Relief of:

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

Oral Suspension/ 4 fl. oz. (120ml)

alcohol free/ dye free

LIQUID

12 Hour

Dosing Cup Included
Wash and let air dry after each use

alcohol free/ dye free

berry FLAVOR

Drug Facts

Active ingredient (in each 5 mL teaspoonful)	Purpose
Fexofenadine HCl 30 mg	Antihistamine

Uses

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

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

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consumers with kidney disease	ask a doctor

Note: teaspoonful = tsp

No change in any Drug Facts language or formatting of approved DFs

Switched the order of "Runny Nose" and "Sneezing" to be consistent with the entire line and the approved PDP for the Allegra Allergy labeling

Font of dosage form and Net Quantity of Contents made slightly bolder

Added a depiction of the dosing cup along with the word "LIQUID" to aid in identifying the dosage form

No change in any Drug Facts language or formatting of approved DFs

The "12 Hour" dosing regimen added to this side panel

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Children's Allegra[®] Allergy

Ages 2 Years & Older **12 Hour**



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Children's Allegra[®] Allergy

Ages 2 Years & Older **12 Hour**

Drug Facts (continued)

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fexofenadine HCl oral suspension
30 mg/5ml antihistamine

Indoor & Outdoor Allergies

Ages 2 Years & Older



LIQUID

12 Hour

Relief of:

- ✓ Runny Nose
- ✓ Sneezing
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- ✓ Itchy Nose or Throat



berry
FLAVOR

**Oral Suspension/
 4 fl. oz. (120ml)**

alcohol free / dye free

NON-DROWSY

Children's Allegra[®] Allergy

Ages 2 Years & Older

12 Hour



Dosing Cup Included
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alcohol free/
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berry
FLAVOR

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LOT

EXP



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Children's Oral Suspension 3-D Carton Rendering With Dimensions



This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
04/28/2013