

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

8 point Helvetica Regular

Title for Continued Panel:
 8 point Helvetica Bold Italic

Bullet:
 5 point
 solid square

2.5 point barline

Title:
 14 point Helvetica Bold
 italic, left justified

Right Justified

Headings:
 8 point Helvetica Bold
 italic, left justified

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

0.5 point hairline

Subheadings:
 6 point Helvetica Bold
 left justified

table format for
 3 or more doses

Graphic leading to
 next panel



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

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

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

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

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

NON-DROWSY
Children's Allegra Allergy
Ages 2 Years & Older **12 Hour**

NON-DROWSY
NDC 41167-4244-4
Children's Allegra Allergy
fexofenadine HCl oral suspension
30 mg/5ml antihistamine
Indoor & Outdoor Allergies

NON-DROWSY
Children's Allegra Allergy
Ages 2 Years & Older
12 Hour

Drug Facts (continued)
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

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
Dosing Cup Included
Wash and let air dry after each use
alcohol free / dye free
berry FLAVOR

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





NON-DROWSY

Children's Allegra[®] Allergy

Ages 2 Years & Older **12 Hour**



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Indoor & Outdoor Allergies

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Ages 2 Years & Older



12 Hour

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- ✓ Sneezing
- ✓ Itchy, Watery Eyes
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LOT

EXP



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