

FOR FDA SUBMISSION ONLY

NON-DROWSY

Children's Allegra® Allergy

Ages 2 Years and Older 12^{HOUR}

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NON-DROWSY

Children's Allegra® Allergy

Ages 2 Years and Older 12^{HOUR}

NON-DROWSY

Children's Allegra® Allergy

Ages 2 Years and 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.
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NON-DROWSY

Children's Allegra® Allergy

Ages 2 Years and Older 12^{HOUR}

NDC 41167-4244-4
 fexofenadine HCl oral suspension 30 mg/5 mL antihistamine
 Indoor and Outdoor Allergies
 alcohol free
 dye free
RELIEF OF:
 ✓ Sneezing
 ✓ Runny Nose
 ✓ Itchy, Watery Eyes
 ✓ Itchy Nose or Throat
 berry flavor
 Oral Suspension / 4 fl. oz. (120 mL)

NON-DROWSY

Children's Allegra® Allergy

Ages 2 Years and Older 12^{HOUR}

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

NON-DROWSY

Children's Allegra® Allergy

Ages 2 Years and Older 12^{HOUR}

LOT

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NON-DROWSY

Children's Allegra® Allergy

Ages 2 Years and 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

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Drug Facts (continued)

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.
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

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 teaspoonsful (10 mL) every 12 hours; do not take more than 4 teaspoonsful (20 mL) in 24 hours
children 6 to under 12 years of age	take 1 teaspoonful (5 mL) every 12 hours; do not take more than 2 teaspoonsful (10 mL) in 24 hours
children under 6 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, edelate disodium, flavor, poloxamer 407, propylene glycol, propylparaben, purified water, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, sucrose, titanium dioxide, xanthan gum, xylitol

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NON-DROWSY

Children's Allegra Hives

Ages 6 Years and Older

NDC 41167-4244-5

Children's Allegra Hives

fexofenadine HCl oral suspension 30 mg/5 mL antihistamine

Ages 6 Years and Older

alcohol free
dye free

berry flavor

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

NON-DROWSY

Children's Allegra Hives

Ages 6 Years and Older

Dosing Cup Included

Wash and let air dry after each use

alcohol free
dye free

berry flavor

FPO

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NON-DROWSY

Children's Allegra Hives

Ages 6 Years and Older

NDC 41167-4244-5

Children's Allegra Hives

fexofenadine HCl oral suspension 30 mg/5 mL antihistamine

Ages 6 Years and Older

alcohol free
dye free

berry flavor

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

FPO

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FOR FDA SUBMISSION ONLY

NDC 41167-4244-4

NON-DROWSY

Children's Allegra® Allergy

Ages 2 Years and Older

RELIEF OF:

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

fexofenadine HCl oral suspension **30 mg/5 ml** antihistamine

Indoor and Outdoor Allergies

Dosing Cup Included
Wash and let air dry after each use

12 HOUR

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

Active ingredient (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

Purpose
■ **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 was 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

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NDC 41167-4244-5
NON-DROWSY

Children's Allegra[®] Hives

Ages 6 Years and Older

fexofenadine HCl oral suspension 30 mg/5 ml antihistamine

Dosing Cup Included
Wash and let air dry after each use

RELIEF OF ITCHING DUE TO HIVES

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

Purpose
Reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Uses reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Warnings Severe Allergy Warning: Get emergency help immediately if you have hives along with any of the following symptoms: ■ trouble swallowing ■ dizziness or loss of consciousness ■ swelling of tongue ■ swelling in or around mouth ■ trouble speaking ■ drooling ■ wheezing or problems breathing. These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional immediately. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later. **Not a Substitute for Epinephrine.** If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times. **Do not use** ■ to prevent hives from any known cause such as: ■ foods ■ insect stings ■ medicines ■ latex or rubber gloves because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause. ■ 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.

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

LOT

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■ hives that are an unusual color, look bruised or blistered ■ hives that do not itch
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. ■ symptoms do not improve after 3 days of treatment ■ the hives have lasted more than 6 weeks **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 6 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 6 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 was opened or 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

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

/s/

ANDREA LEONARD SEGAL
01/24/2011