

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
201373Orig1s000

LABELING

NON-DROWSY

Children's Allegra® Allergy

Ages 2 Years and Older 12 HOUR



995760

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

NDC 41167-4244-4

Children's Allegra® Allergy

fexofenadine HCl oral suspension 30 mg/5 ml antihistamine

Indoor and Outdoor Allergies

Ages 2 Years and Older

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



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

Drug Facts

| Active ingredient | 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

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 and Older 12 HOUR



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EXP

NON-DROWSY

Children's Allegra® Allergy

Ages 2 Years and Older



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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 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 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

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NON-DROWSY

Children's Allegra Hives

Ages 6 Years and Older 12 HOUR

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



RELIEF OF ITCHING DUE TO HIVES

berry flavor

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



Dosing Cup Included

Wash and let air dry after each use

alcohol free
dye free

berry flavor



XXXX60

NON-DROWSY

Children's Allegra Hives

Ages 6 Years and Older

NON-DROWSY

alcohol free
dye free

berry flavor

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



RELIEF OF ITCHING DUE TO HIVES

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NON-DROWSY

Children's Allegra Hives

Ages 6 Years and Older

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alcohol free
dye free

berry flavor

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FOR FDA SUBMISSION ONLY

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NON-DROWSY

Children's Allegra® Allergy

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

Indoor and Outdoor Allergies

Dosing Cup Included
Wash and let air dry after each use

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

Ages 2 Years and Older

RELIEF OF:

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

| | | |
|--|--|---|
| <p>Active ingredient (in each 5 mL teaspoonful) Fexofenadine HCl 30 mg.....Antihistamine</p> <p>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</p> | <p>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</p> <p>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</p> | <p style="text-align: right;">50094565</p> <div style="border: 1px solid black; padding: 5px; margin-top: 5px;"> <p style="margin: 0;">LOT</p> <p style="margin: 0;">EXP</p> </div> |
|--|--|---|

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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

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

NON-DROWSY

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

Purpose
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.

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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LOT

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