

Children's Allegra Allergy 12hr ODT  
 ALG\_K\_12hr\_V1\_ODTvert-01

**Children's Allegra Allergy**  
 Ages 6 Years & Older  
**12 Hour**  
 NON-DROWSY  
 12 Orally Disintegrating Tablets

NDC 41167-4233-3

**Children's Allegra Allergy**  
 Ages 6 Years & Older  
**12 Hour**  
 NON-DROWSY

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orange cream FLAVOR

12 Orally Disintegrating Tablets

ODTvert-01

**Children's Allegra Allergy**  
 Ages 6 Years & Older  
**12 Hour**

Relief of:

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

12 Orally Disintegrating Tablets

Dissolves without water

LOT:  
 EXP:

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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**Children's Allegra Allergy**  
**12 Hour**

**Drug Facts**

Active ingredient (in each tablet)	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. 1

**Directions**  
 ■ place 1 tablet on tongue; tablet disintegrates, with or without water

adults and children 12 years of age and over	take 2 tablets every 12 hours on an empty stomach; do not take more than 4 tablets in 24 hours
children 6 to under 12 years of age	take 1 tablet every 12 hours on an empty stomach; do not take more than 2 tablets in 24 hours
children under 6 years of age	do not use
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

**Other information**

- each tablet contains: sodium 5 mg
- phenyletomerics: contains phenylalanine 5.3 mg per tablet
- safety sealed: do not use if carton is opened or if individual blister units are torn or opened
- store between 20° and 25°C (68° and 77°F)
- use tablet immediately after opening individual blister

**Inactive ingredients**  
 aspartame, citric acid anhydrous, crospovidone, flavors, magnesium stearate, mannitol, methacrylic acid copolymer, microcrystalline cellulose, povidone, sodium bicarbonate, sodium starch glycolate

**Questions or comments?**  
 call toll-free 1-800-633-1610 or [www.allegra.com](http://www.allegra.com)

**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

0.5 point hairline

table format for 3 or more doses

**Bullet:**  
 5 point  
 solid square

2.5 point barline

The carton orientation at Point of Sale (on store shelf) changed from horizontal to vertical

The Proprietary Name, established name/dosage all centered on the PDP

Added name and 12Hour designation on rear panel

Format of the Drug Facts changed to a single column from two columns; no language was changed

The 12Hour designation repositioned from right side of top panel

Children's  
Allegra<sup>®</sup>  
Allergy  
Ages 6 Years  
& Older  
12 Hour

NDC 41167-4233-3

NON-DROWSY

12 Orally Disintegrating Tablets

Children's  
Allegra<sup>®</sup>  
Allergy

fexofenadine HCl orally disintegrating tablet 30 mg/antihistamine

Indoor and Outdoor Allergies

Children's  
Allegra<sup>®</sup>  
Allergy  
Ages 6 Years  
& Older  
12 Hour

The makers of Allegra<sup>®</sup> do not make store brand products. The trade dress of this Allegra<sup>®</sup> package is subject to trademark protection.

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Chattanooga, TN  
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Children's  
Allegra<sup>®</sup>  
Allergy  
12 Hour

### Drug Facts

**Active ingredient (in each tablet)**  
Fexofenadine HCl 30 mg

**Purpose**  
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**  
■ place 1 tablet on tongue; tablet disintegrates, with or without water

adults and children 12 years of age and over	take 2 tablets every 12 hours on an empty stomach; do not take more than 4 tablets in 24 hours
children 6 to under 12 years of age	take 1 tablet every 12 hours on an empty stomach; do not take more than 2 tablets in 24 hours
children under 6 years of age	do not use
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

**Other information**  
■ each tablet contains: sodium 5 mg  
■ phenylketonurics: contains phenylalanine 5.3 mg per tablet  
■ safety sealed: do not use if carton is opened or if individual blister units are torn or opened  
■ store between 20° and 25°C (68° and 77°F)  
■ use tablet immediately after opening individual blister

**Inactive ingredients**  
aspartame, citric acid anhydrous, crospovidone, flavors, magnesium stearate, mannitol, methacrylic acid copolymer, microcrystalline cellulose, povidone, sodium bicarbonate, sodium starch glycolate

**Questions or comments?**  
call toll-free 1-800-633-1610 or [www.allegra.com](http://www.allegra.com)

The Proprietary Name and age designation now oriented in a stacked manner to accommodate narrower side panels

orange  
cream  
FLAVOR

12 Orally Disintegrating Tablets

Flavor designation and depiction and Net Quantity of Contents added to side panel

ODTvert-01

Ages 6 Years  
& Older



Tablets

12 Hour

Relief of:

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

12 Orally Disintegrating Tablets

orange  
cream  
FLAVOR

Dissolves without water

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 a tablet along with the word "Tablets" to aid in identifying the dosage form

Repositioned "Dissolves without water"



# Children's Orally Disintegrating Tablets 3-D Carton Rendering With Dimensions





No change to any of the approved Drug Facts language or formatting

**Drug Facts**  
Active ingredient (in each tablet) Fexofenadine HCl 30 mg ..... Antihistamine  
Purpose  
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.  
Inactive ingredients  
aspartame, citric acid anhydrous, croscopolone, flavors, magnesium stearate, mannitol, methacrylic acid copolymer, microcrystalline cellulose, povidone, sodium bicarbonate, sodium starch glycolate  
Questions or comments?  
call toll-free 1-800-633-1610 or [www.allegra.com](http://www.allegra.com)  
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0044961-01

**Children's Allegra Allergy**  
Ages 6 Years & Older  
12 Hour  
18 Orally Disintegrating Tablets  
NON-DROWSY

**BONUS!**  
6 FREE Orally Disintegrating Tablets

**Children's Allegra Allergy**  
Ages 6 Years & Older  
12 Hour  
18 Orally Disintegrating Tablets  
NDC 41167-4233-3  
Ages 6 Years & Older  
12 Hour  
Relief of:  
✓ Runny Nose  
✓ Sneezing  
✓ Itchy, Watery Eyes  
✓ Itchy Nose or Throat  
18 Orally Disintegrating Tablets  
Dissolves without water  
Orange cream FLAVOR

**Children's Allegra Allergy**  
Ages 6 Years & Older  
12 Hour  
The makers of Allegra® do not make store brand products. The trade dress of this Allegra® package is subject to trademark protection.

Removed "Original Prescription Strength" and repositioned "NON-DROWSY" accordingly

Net Quantity of Contents necessarily changed

Removed "Original Prescription Strength" and repositioned "NON-DROWSY" accordingly

NDC number repositioned to allow for the Bonus flag

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

Net Quantity of Contents necessarily changed

Repositioned "Dissolves without water" from bottom left of carton

The 12Hour designation repositioned from right side of top panel

Bonus flag added

**Drug Facts** (continued)

**Directions**  
 ■ place 1 tablet on tongue; tablet disintegrates, with or without water

**12 years of age and over**  
 take 2 tablets every 12 hours on an empty stomach; do not take more than 4 tablets in 24 hours.

**children 6 to under 12 years of age**  
 take 1 tablet every 12 hours on an empty stomach; do not take more than 2 tablets in 24 hours.

**children under 6 years of age**  
 do not use

**adults 65 years of age and older**  
 ask a doctor

do not use consumers with kidney disease ask a doctor

**Warnings**  
 Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

**Asks 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)  
 ■ do not take with full 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.

**Other information**  
 ■ each tablet contains: sodium 5 mg  
 ■ phenylethanolamines: contains phenylethanolamine 5.3 mg per tablet  
 ■ safety sealed: do not use if carton is opened or if individual blister units are torn or opened  
 ■ store between 20° and 25°C (68° and 77°F)  
 ■ use tablet immediately after opening individual blister

**Inactive ingredients**  
 aspartame, citric acid anhydrous, croscopolone, flavors, magnesium stearate, mannitol, methacrylic acid copolymer, microcrystalline cellulose, polydextrose, sodium bicarbonate, sodium starch glycolate

**Questions or comments?**  
 call toll-free 1-800-633-1610 or [www.allegra.com](http://www.allegra.com)

**Active ingredient (in each tablet)**  
 Fexofenadine HCl 30 mg  
 Antihistamine

**Uses**  
 temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
 ■ itchy, watery eyes  
 ■ runny nose  
 ■ sneezing  
 ■ itching of the nose or throat

**Drug Facts**

**Active ingredient (in each tablet)**  
 Fexofenadine HCl 30 mg  
 Antihistamine

**Purpose**

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**Children's**  
**Allegra® Allergy**  
 Ages 6 Years & Older  
**12 Hour**

**NON-DROWSY**

**12 18** Orally Disintegrating Tablets

**BONUS!**  
**6 FREE** Orally Disintegrating Tablets

**Children's**  
**Allegra® Allergy**  
 fexofenadine HCl orally disintegrating tablet 30 mg/antihistamine  
**Indoor and Outdoor Allergies**

**Children's**  
**Allegra® Allergy**

**Children's**  
**Allegra® Allergy**  
 Ages 6 Years & Older  
**12 Hour**

**NON-DROWSY**

NDC 41167-4233-3

**Ages 6 Years & Older**

**12 Hour**

Relief of:

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

**12 18** Orally Disintegrating Tablets  
 Dissolves without water

**orange cream**  
 FLAVOR

**Children's**  
**Allegra® Allergy**  
 Ages 6 Years & Older

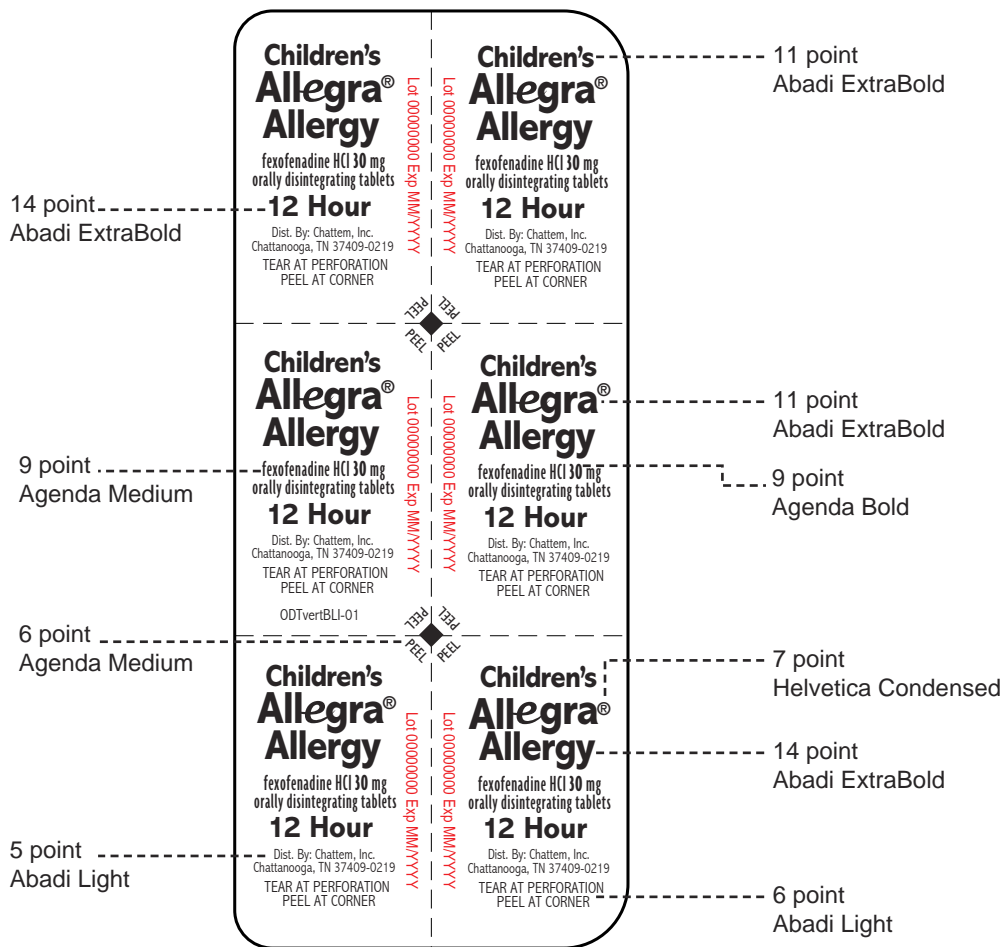
The makers of Allegra® do not make store brand products. The trade dress of this Allegra® package is subject to trademark protection.

**BAR CODE**  
**FPO**

# Children's Allegra Oral Dissintegrating Tablets

## VERTICAL BLISTER

ALG\_K 12hr\_BLI\_ODTvert



**Children's Allegra® Allergy**  
fexofenadine HCl 30 mg orally disintegrating tablets  
**12 Hour**  
Dist. By: Chattem, Inc.  
Chattanooga, TN 37409-0219  
TEAR AT PERFORATION  
PEEL AT CORNER

**Children's Allegra® Allergy**  
fexofenadine HCl 30 mg orally disintegrating tablets  
**12 Hour**  
Dist. By: Chattem, Inc.  
Chattanooga, TN 37409-0219  
TEAR AT PERFORATION  
PEEL AT CORNER

**Children's Allegra® Allergy**  
fexofenadine HCl 30 mg orally disintegrating tablets  
**12 Hour**  
Dist. By: Chattem, Inc.  
Chattanooga, TN 37409-0219  
TEAR AT PERFORATION  
PEEL AT CORNER

**Children's Allegra® Allergy**  
fexofenadine HCl 30 mg orally disintegrating tablets  
**12 Hour**  
Dist. By: Chattem, Inc.  
Chattanooga, TN 37409-0219  
TEAR AT PERFORATION  
PEEL AT CORNER

Lot: 000000000 Exp: MM/YYYY

Lot: 000000000 Exp: MM/YYYY

Lot: 000000000 Exp: MM/YYYY

Lot: 000000000 Exp: MM/YYYY

OTVertBLI-01

TEAR PEEL

TEAR PEEL

TEAR PEEL

TEAR PEEL

The blister orientation is now vertical to align with the proposed orientation of the carton

Proprietary name is stacked on 3 lines instead of 2, and words are centered

<p><b>Children's Allegra® Allergy</b> fexofenadine HCl 30 mg orally disintegrating tablets <b>12 Hour</b> Dist. By: Chattem, Inc. Chattanooga, TN 37409-0219 TEAR AT PERFORATION PEEL AT CORNER</p>	<p>Lot: 000000000 Exp: MM/YYYY Lot: 000000000 Exp: MM/YYYY</p>	<p><b>Children's Allegra® Allergy</b> fexofenadine HCl 30 mg orally disintegrating tablets <b>12 Hour</b> Dist. By: Chattem, Inc. Chattanooga, TN 37409-0219 TEAR AT PERFORATION PEEL AT CORNER</p>
<p><b>Children's Allegra® Allergy</b> fexofenadine HCl 30 mg orally disintegrating tablets <b>12 Hour</b> Dist. By: Chattem, Inc. Chattanooga, TN 37409-0219 TEAR AT PERFORATION PEEL AT CORNER ODTvertBLL-01</p>	<p>Lot: 000000000 Exp: MM/YYYY Lot: 000000000 Exp: MM/YYYY</p>	<p><b>Children's Allegra® Allergy</b> fexofenadine HCl 30 mg orally disintegrating tablets <b>12 Hour</b> Dist. By: Chattem, Inc. Chattanooga, TN 37409-0219 TEAR AT PERFORATION PEEL AT CORNER</p>
<p><b>Children's Allegra® Allergy</b> fexofenadine HCl 30 mg orally disintegrating tablets <b>12 Hour</b> Dist. By: Chattem, Inc. Chattanooga, TN 37409-0219 TEAR AT PERFORATION PEEL AT CORNER</p>	<p>Lot: 000000000 Exp: MM/YYYY Lot: 000000000 Exp: MM/YYYY</p>	<p><b>Children's Allegra® Allergy</b> fexofenadine HCl 30 mg orally disintegrating tablets <b>12 Hour</b> Dist. By: Chattem, Inc. Chattanooga, TN 37409-0219 TEAR AT PERFORATION PEEL AT CORNER</p>

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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.**

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/s/

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JOEL SCHIFFENBAUER  
04/28/2013