

Children's Allegra Allergy 12hr ODT
ALG_K_12hr_V1_ODTvert-01

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

NON-DROWSY

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

orange cream FLAVOR

12 Orally Disintegrating Tablets

ODTvert-01

NDC 41167-4233-3

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

fefenadine HCl orally disintegrating tablet 30 mg/antihistamine

Indoor and Outdoor Allergies

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:

NON-DROWSY

Children's Allegra Allergy **12 Hour**

Drug Facts

Active ingredient (in each tablet) **Purpose**
Fexofenadine HCl 30 mgAntihistamine

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
■ phenyleketonics: 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

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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Chattanooga, TN
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0 41167 42333 2

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

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

The 12Hour designation repositioned from right side of top panel

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

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

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

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
Allegra Allergy
Ages 6 Years & Older
12 Hour

NON-DROWSY

12 Orally Disintegrating Tablets

NDC 41167-4233-3

NON-DROWSY

Children's
Allegra Allergy

Ages 6 Years & Older

12 Hour

Children's Allegra Allergy

fenofenadine HCl orally disintegrating tablet 30 mg/antihistamine

Indoor and Outdoor Allergies



12 Orally Disintegrating Tablets

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

Dissolves without water

Children's
Allegra Allergy

Ages 6 Years & Older

12 Hour

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Children's
Allegra Allergy

12 Hour

Drug Facts

Active ingredient (in each tablet) Purpose
Fexofenadine HCl 30 mgAntihistamine

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

LOT:

EXP:

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



Children's Allegra Oral Dissintegrating Tablets- BONUS CTN
 ALG_12hrODT_18ctBonus_CTN



Title:
 14 point Helvetica Bold
 italic, left justified

Headings:
 8 point Helvetica Bold
 italic, left justified

Bullet:
 5 point
 solid square

0.5 point hairline

Subheadings:
 6 point Helvetica Bold
 left justified

Right Justified

Graphic leading
 to next panel

Title for Continued Panel:
 8 point Helvetica Bold Italic

table format for
 3 or more doses

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

2.5 point barline

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 ■ 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.

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Drug Facts (continued)

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

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



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

Active ingredient (in each tablet)
Fexofenadine HCl 30 mgAntihistamine

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

- runny nose
- 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)
- 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.

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0044961-01

Drug Facts (continued)

Directions

- place 1 tablet on tongue; tablet disintegrates, with or without water
- adults and children 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
- phenylethanolamine: 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, povidone, sodium bicarbonate, sodium starch glycolate

Questions or comments?
Call toll-free 1-800-633-1610 or www.allegra.com

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
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

LOT
EXP

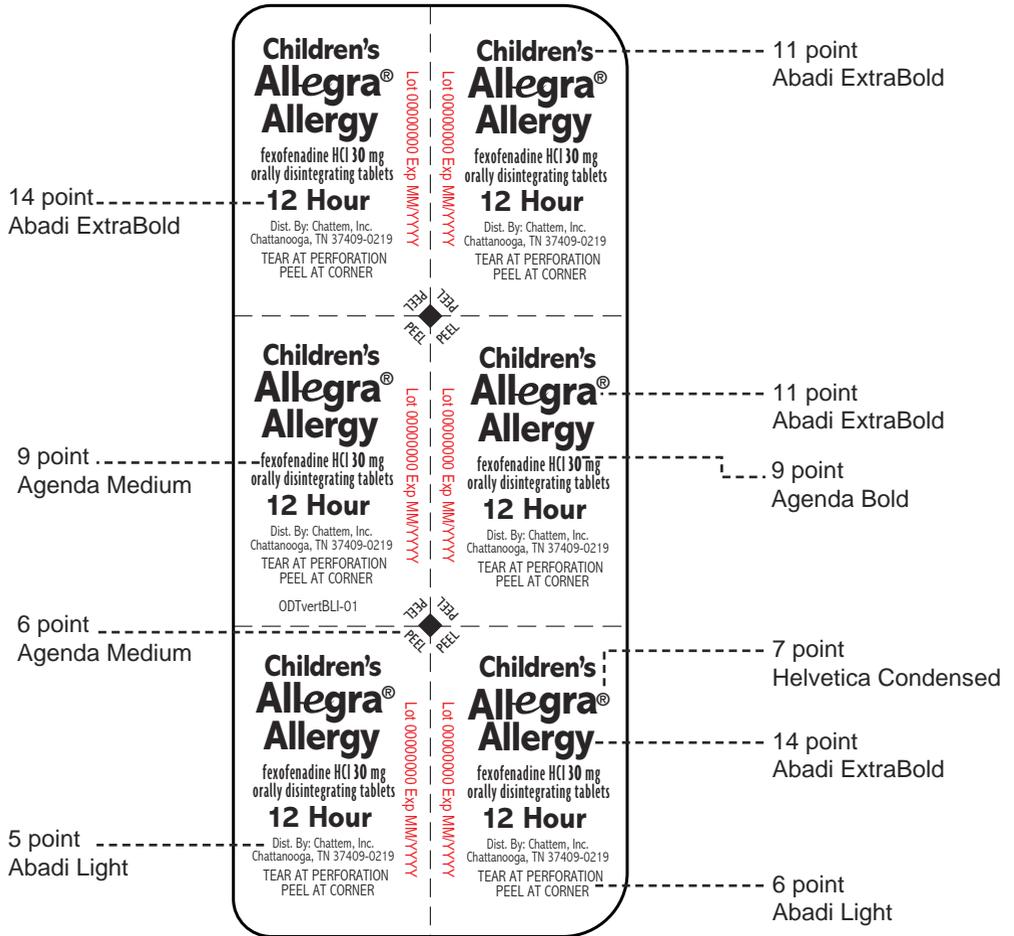
Children's Allegra® Allergy
Ages 6 Years & Older

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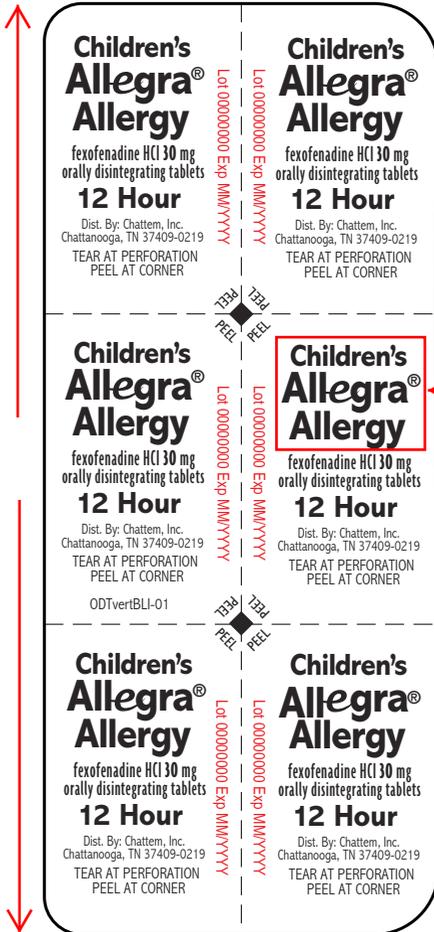
BAR CODE
FPO

Children's Allegra Oral Dissintegrating Tablets VERTICAL BLISTER

ALG_K 12hr_BLI_ODTvert



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

Children's Allegra® Allergy

fexofenadine HCl 30 mg orally disintegrating tablets

12 Hour

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TEAR AT PERFORATION
PEEL AT CORNER

Lot 000000000 Exp MM/YYYY

Lot 000000000 Exp MM/YYYY

Children's Allegra® Allergy

fexofenadine HCl 30 mg orally disintegrating tablets

12 Hour

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Chattanooga, TN 37409-0219

TEAR AT PERFORATION
PEEL AT CORNER

PEEL
PEEL

PEEL
PEEL

Children's Allegra® Allergy

fexofenadine HCl 30 mg orally disintegrating tablets

12 Hour

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TEAR AT PERFORATION
PEEL AT CORNER

Lot 000000000 Exp MM/YYYY

Lot 000000000 Exp MM/YYYY

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fexofenadine HCl 30 mg orally disintegrating tablets

12 Hour

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TEAR AT PERFORATION
PEEL AT CORNER

PEEL
PEEL

PEEL
PEEL

Children's Allegra® Allergy

fexofenadine HCl 30 mg orally disintegrating tablets

12 Hour

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TEAR AT PERFORATION
PEEL AT CORNER

Lot 000000000 Exp MM/YYYY

Lot 000000000 Exp MM/YYYY

Children's Allegra® Allergy

fexofenadine HCl 30 mg orally disintegrating tablets

12 Hour

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Chattanooga, TN 37409-0219

TEAR AT PERFORATION
PEEL AT CORNER

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/s/

JOEL SCHIFFENBAUER
04/28/2013