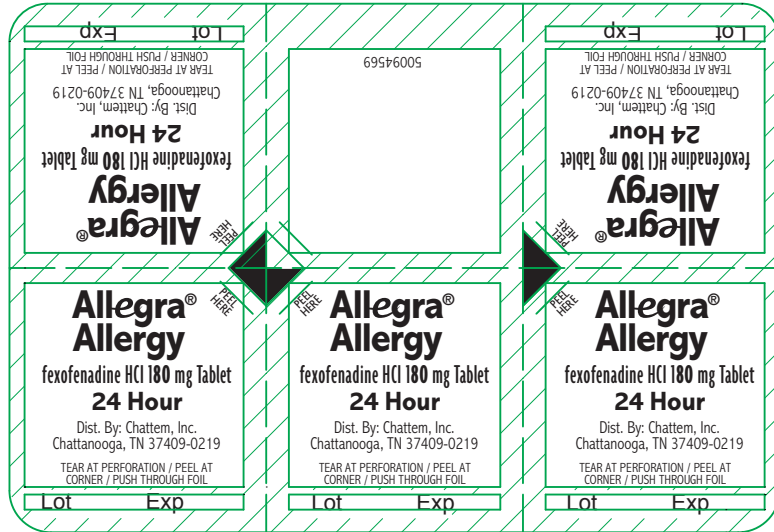
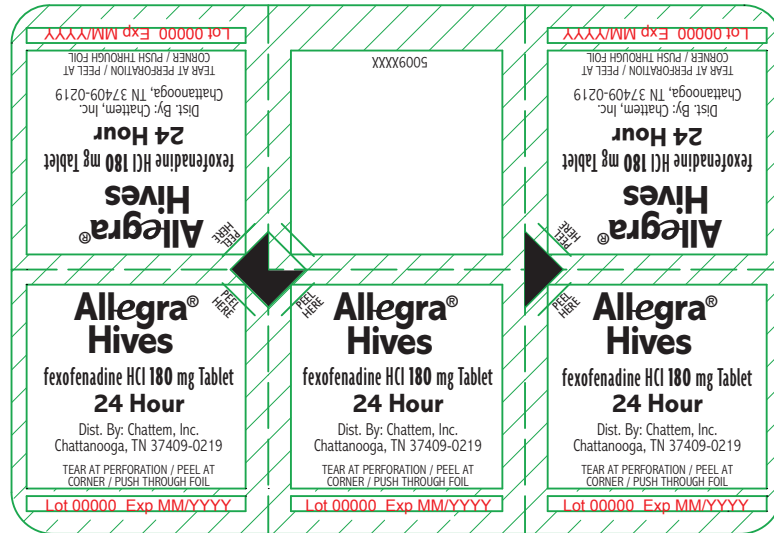


FOR FDA SUBMISSION ONLY



FOR FDA SUBMISSION ONLY



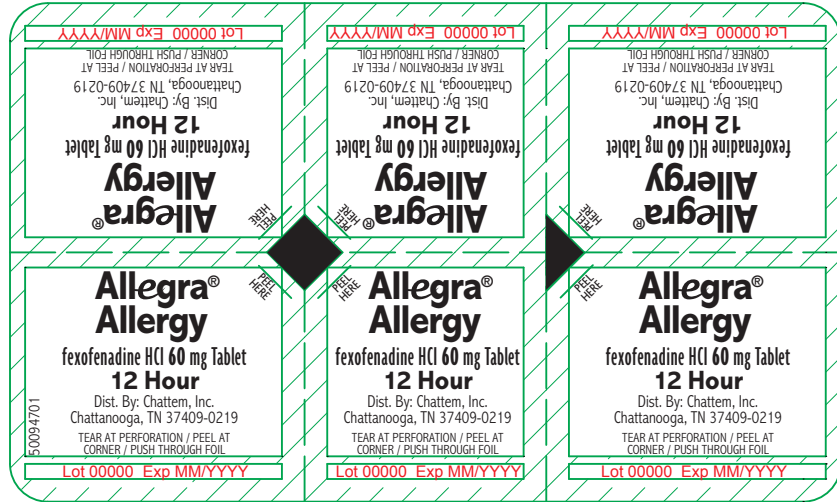
FOR FDA SUBMISSION ONLY



FOR FDA SUBMISSION ONLY



FOR FDA SUBMISSION ONLY



FOR FDA SUBMISSION ONLY



FOR FDA SUBMISSION ONLY

Allegra[®] Allergy

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

24_{HOUR}

NDC 41167-4120-2

Allegra[®] Allergy

fexofenadine HCl tablet 180 mg/antihistamine

Indoor and Outdoor Allergies

15 Tablets 180 mg each

Allegra[®] Allergy

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

0 41167 41238 1

Dist. By: Chatterm, Inc. (part of the sanofi-aventis Group), Chattanooga, TN 37409-0219 ©2010 50094571

LOT
EXP

Allegra[®] Allergy

24_{HOUR}

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

Allegra[®] Allergy

Drug Facts

Active ingredient (in each tablet)
Fexofenadine HCl 180 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

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.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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

Drug Facts (continued)

Directions
 adults and children 12 years of age and over
 take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours

children under 12 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
 ■ 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)
 ■ protect from excessive moisture

Inactive ingredients
 colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide blends, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, titanium dioxide

FOR FDA SUBMISSION ONLY

**Allegra®
Allergy**

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY



**1 BOTTLE
INSIDE**

24 HOUR

NDC 41167-4120-3

**Allegra®
Allergy**

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

feoxetine HCl tablet 180 mg/antihistamine

Indoor and Outdoor Allergies

30 Tablets 180 mg each

24 HOUR

RELIEF OF:

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





895760

Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Fexofenadine HCl 180 mg..... Antihistamine		Directions	
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat 		adults and children 12 years of age and over	take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours
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.		children under 12 years of age	do not use
When using this product <ul style="list-style-type: none"> ■ 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) 		adults 65 years of age and older	ask a doctor
Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.		consumers with kidney disease	ask a doctor
If pregnant or breast-feeding , ask a health professional before use.		Other information <ul style="list-style-type: none"> ■ 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) ■ protect from excessive moisture 	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ▶		Inactive ingredients colloidal silicone dioxide, croscarmellose sodium, hypromellose, iron oxide blends, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, titanium dioxide	
		Questions or comments? call toll-free 1-800-633-1610 or www.allegra.com	



0 41167 41251 0

FOR FDA SUBMISSION ONLY

Allegra[®] Allergy

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

1 BOTTLE INSIDE

24 HOUR

NDC 41167-4120-4

Allegra[®] Allergy

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

fexofenadine HCl tablet 180 mg/antihistamine

Indoor and Outdoor Allergies

24 HOUR

45 Tablets 180 mg each

RELIEF OF:

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

LOT

EXP

866260

1 BOTTLE INSIDE
Actual Size

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

Allegra[®] Allergy

fexofenadine HCl tablet
180 mg/
antihistamine

Indoor and Outdoor Allergies

24 HOUR

45 Tablets 180 mg each

NDC 41167-4120-4

24 HOUR

LOT

EXP

866260

Drug Facts

Active ingredient (in each tablet) Purpose
Fexofenadine HCl 180 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. ▶

The makers of Allegra[®] do not make store brand products. The trade dress of this Allegra[®] package is subject to trademark protection.
Dist. By: Chatterm, Inc. (part of the sanofi-aventis Group), Chattanooga, TN 37409-0219 ©2010 50092998

FOR FDA SUBMISSION ONLY



FOR FDA SUBMISSION ONLY

**Allegra®
Allergy**

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY



**2 BOTTLES
INSIDE**

24 HOUR

NDC 41167-4120-5

**Allegra®
Allergy**

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

fexofenadine HCl tablet 180 mg/antihistamine
Indoor and Outdoor Allergies

90 Tablets 180 mg each

24 HOUR

RELIEF OF:

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





266260

Drug Facts		Drug Facts (continued)									
<p>Active ingredient (in each tablet) Purpose Fexofenadine HCl 180 mg..... Antihistamine</p>		<p>Directions</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">adults and children 12 years of age and over</td> <td style="width: 50%;">take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours</td> </tr> <tr> <td>children under 12 years of age</td> <td>do not use</td> </tr> <tr> <td>adults 65 years of age and older</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with kidney disease</td> <td>ask a doctor</td> </tr> </table>		adults and children 12 years of age and over	take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours	children under 12 years of age	do not use	adults 65 years of age and older	ask a doctor	consumers with kidney disease	ask a doctor
adults and children 12 years of age and over	take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours										
children under 12 years of age	do not use										
adults 65 years of age and older	ask a doctor										
consumers with kidney disease	ask a doctor										
<p>Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> <li style="width: 50%;">■ runny nose <li style="width: 50%;">■ itchy, watery eyes <li style="width: 50%;">■ sneezing <li style="width: 50%;">■ itching of the nose or throat 		<p>Other information</p> <ul style="list-style-type: none"> ■ 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) ■ protect from excessive moisture 									
<p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ 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) <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ►</p>		<p>Inactive ingredients colloidal silicone dioxide, croscarmellose sodium, hypromellose, iron oxide blends, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, titanium dioxide</p> <p>Questions or comments? call toll-free 1-800-633-1610 or www.allegra.com</p>									

The makers of Allegra® do not make store brand products. The trade dress of this Allegra® package is subject to trademark protection.
 Dist. By: Chatterm, Inc. (part of the sanofi-aventis Group), Chattanooga, TN 37409-0219 ©2010 50092997

**Allegra®
Allergy**

NDC 41167-4120-5

**Allegra®
Allergy**

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

fexofenadine HCl tablet 180 mg/antihistamine
Indoor and Outdoor Allergies

90 Tablets 180 mg each



0 41167 41290 9



266260

Drug Facts		Drug Facts (continued)									
<p>Active ingredient (in each tablet) Purpose Fexofenadine HCl 180 mg..... Antihistamine</p>		<p>Directions</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">adults and children 12 years of age and over</td> <td style="width: 50%;">take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours</td> </tr> <tr> <td>children under 12 years of age</td> <td>do not use</td> </tr> <tr> <td>adults 65 years of age and older</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with kidney disease</td> <td>ask a doctor</td> </tr> </table>		adults and children 12 years of age and over	take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours	children under 12 years of age	do not use	adults 65 years of age and older	ask a doctor	consumers with kidney disease	ask a doctor
adults and children 12 years of age and over	take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours										
children under 12 years of age	do not use										
adults 65 years of age and older	ask a doctor										
consumers with kidney disease	ask a doctor										
<p>Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> <li style="width: 50%;">■ runny nose <li style="width: 50%;">■ itchy, watery eyes <li style="width: 50%;">■ sneezing <li style="width: 50%;">■ itching of the nose or throat 		<p>Other information</p> <ul style="list-style-type: none"> ■ 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) ■ protect from excessive moisture 									
<p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ 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) <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ►</p>		<p>Inactive ingredients colloidal silicone dioxide, croscarmellose sodium, hypromellose, iron oxide blends, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, titanium dioxide</p> <p>Questions or comments? call toll-free 1-800-633-1610 or www.allegra.com</p>									

The makers of Allegra® do not make store brand products. The trade dress of this Allegra® package is subject to trademark protection.
 Dist. By: Chatterm, Inc. (part of the sanofi-aventis Group), Chattanooga, TN 37409-0219 ©2010 50092997

FOR FDA SUBMISSION ONLY

Children's Allegra® Allergy
Ages 6 Years and Older

NDC 41167-4222-2

Children's Allegra® Allergy

fexofenadine HCl tablet
30 mg/antihistamine

Indoor and Outdoor Allergies

6 Tablets 30 mg each

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

12HOUR

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

12HOUR

RELIEF OF:

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

Children's Allegra® Allergy Ages 6 Years and Older

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



0 41167 42222 6

Dist. By: Chatterm, Inc. (part of the sanofi-aventis Group), Chattanooga, TN 37409-0219 ©2010

50094531

call toll-free 1-800-633-1610 or www.allegra.com

Questions or comments?

help or contact a Poison Control Center 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.

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

- do not take with fruit juices (see Directions)
- do not take at the same time as aluminum or magnesium antacids
- do not take more than directed

When using this product

- should determine if you need a different dose.

Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.

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

Warnings

- sneezing
- runny nose
- itchy, watery eyes
- itching of the nose or throat

Uses

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

- sneezing
- runny nose
- itchy, watery eyes
- itching of the nose or throat

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

Purpose Antihistamine

Directions

adults and children 12 years of age and over	take two 30 mg tablets with water every 12 hours; do not take more than 4 tablets in 24 hours
children 6 to under 12 years of age	take one 30 mg tablet with water every 12 hours; 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

- 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)
- protect from excessive moisture

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide blends, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, titanium dioxide

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

Children's Allegra® Allergy Ages 6 Years and Older

FOR FDA SUBMISSION ONLY



**Allegra[®]
Allergy**

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

12 HOUR

NDC 41167-4131-2

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

**Allegra[®]
Allergy**

fexofenadine HCl tablet 60 mg/antihistamine
Indoor and Outdoor Allergies

RELIEF OF:
 ✓ Sneezing
 ✓ Runny Nose
 ✓ Itchy, Watery Eyes
 ✓ Itchy Nose
 or Throat

12 HOUR

12 Tablets 60 mg each

**Allegra[®]
Allergy**



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



Dist. By: Chatham, Inc. (part of the sanofi-aventis group), Chattanooga, TN 37409-0219 ©2010
 50094533

Drug Facts (continued)

Directions
 adults and children
 take one 60 mg tablet with water
 every 12 hours; do not take more
 than 2 tablets in 24 hours
 and over

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.

Other Information
 ■ 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)
 ■ protect from excessive moisture

Inactive ingredients
 colloidal silicon dioxide, croscarmellose sodium, hypromellose,
 from oxide blends, magnesium stearate, microcrystalline
 cellulose, polyethylene glycol, povidone, pregelatinized starch,
 titanium dioxide

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

Drug Facts

Active ingredient (in each tablet)
 Fexofenadine HCl 60 mg Antihistamine

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

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

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

12 HOUR

**Allegra[®]
Allergy**

FOR FDA SUBMISSION ONLY

Drug Facts (continued)

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
 ■ trouble swallowing ■ swelling in or around mouth
 ■ swelling of tongue ■ swelling in or around mouth
 ■ trouble speaking ■ drooling ■ wheezing or problems breathing

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

Drug Facts

Active ingredient (in each tablet)
 Fexofenadine HCl 180 mg.....Antihistamine

NDC 41167-4120-6

Allegra Hives

RELIEF OF ITCHING DUE TO HIVES

fexofenadine HCl tablet 180 mg/antihistamine

24 HOUR

5 Tablets 180 mg each

Drug Facts (continued)

Inactive ingredients
 colloidal silicone dioxide, croscarmellose sodium, hypromellose, iron oxide blends, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, titanium dioxide

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

0 00000 00000 0



Drug Facts (continued)

Stop use and ask a doctor if
 ■ an allergic reaction to this product occurs. Seek medical help right away.

Directions
 adults and children
 take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours

children under 12 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
 ■ 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°)
 ■ protect from excessive moisture

Drug Facts (continued)

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.
 ■ 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)

Allegra Hives

ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY

The makers of Allegra® do not make store brand products. The trade dress of this Allegra® package is subject to trademark protection. Dist. By: Chaittem, Inc. (part of the sanofi-aventis Group), Chattanooga, TN 37409-0219 ©2010

FOR FDA SUBMISSION ONLY

Drug Facts (continued)

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

adults and children 12 years of age and over	take two 30 mg tablets with water every 12 hours; do not take more than 4 tablets in 24 hours
children 6 to under 12 years of age	take one 30 mg tablet with water every 12 hours; 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

- safely 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)
- protect from excessive moisture

▲

Drug Facts (continued)

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.
- 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)

▲

0 00000 00000 0



0 00000 00000 0

Drug Facts (continued)

Inactive ingredients

colloidal silicone dioxide, croscarmellose sodium, hypromellose, iron oxide blends, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, titanium dioxide

Questions or comments?

call toll-free 1-800-633-1610 or www.allegra.com

5009XXXX

Drug Facts

Active ingredient (in each tablet)


Fexofenadine HCl 30 mg..... Antihistamine

Purpose

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

▲

5009XXXX



5009XXXX

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

Children's Allegra Hives

Ages 6 Years and Older

RELIEF OF ITCHING DUE TO HIVES

12 HOUR

6 Tablets 30 mg each

fexofenadine HCl tablet
30 mg/antihistamine

NDC 41167-4222-3

Drug Facts (continued)

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.
- 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)

▲

Children's Allegra Hives

Ages 6 Years and Older

The makers of Allegra® do not make store brand products. The trade dress of this Allegra® package is subject to trademark protection. Dist. By: Chiltern, Inc. (part of the sanofi-sintelabo Group) Chattanooga, TN 37409-0219 ©2010

FOR FDA SUBMISSION ONLY

**Allegra®
Hives**

The makers of Allegra® do not make store brand products. The trade dress of this Allegra® package is subject to trademark protection. Dist. By: Chatham, Inc. (part of the sanofi-aventis Group), Duluth, GA, TN 37409-0219 ©2010

Drug Facts (continued)

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.
- 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)

Drug Facts (continued)

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

adults and children 12 years of age and over	take one 60 mg tablet with water every 12 hours; do not take more than 2 tablets in 24 hours
children under 12 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

- 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)
- protect from excessive moisture

Drug Facts (continued)

Inactive ingredients
 colloidal silicone dioxide, croscarmellose sodium, hypromellose, iron oxide blends, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, titanium dioxide

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

5009XXXX

12 HOUR

RELIEF OF ITCHING DUE TO HIVES

FPO

5009XXXX

NDC 41167-4131-3

ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY

fexofenadine HCl tablet 60 mg/antihistamine

12 Tablets 60 mg each

Allegra®
Hives

FPO

5009XXXX

<p>Drug Facts</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; padding: 2px;">Active ingredient (in each tablet)</th> <th style="text-align: left; padding: 2px;">Purpose</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Fexofenadine HCl 60 mg.....</td> <td style="padding: 2px;">Antihistamine</td> </tr> </tbody> </table> <p>Uses reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.</p>	Active ingredient (in each tablet)	Purpose	Fexofenadine HCl 60 mg.....	Antihistamine	<p>Drug Facts (continued)</p> <p>Warnings Severe Allergy Warning: Get emergency help immediately if you have hives along with any of the following symptoms:</p> <ul style="list-style-type: none"> ■ trouble swallowing ■ dizziness or loss of consciousness ■ swelling of tongue ■ swelling in or around mouth ■ trouble speaking ■ drooling ■ wheezing or problems breathing
Active ingredient (in each tablet)	Purpose				
Fexofenadine HCl 60 mg.....	Antihistamine				

FOR FDA SUBMISSION ONLY

<p>ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY</p> <p>NDC 41167-4120-3</p> <h1>Allegra®</h1> <h2>Allergy</h2> <p>fexofenadine HCl tablet</p> <p>180 mg/ antihistamine</p> <p>24 HOUR</p> <p>Indoor and Outdoor Allergies</p> <p>30 Tablets 180 mg each</p>	<p>Active ingredient (in each tablet) Fexofenadine HCl 180 mg</p> <p>Purpose Antihistamine</p> <p>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</p> <p>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</p>	<p>contact a Poison Control Center right away.</p> <p>Directions ■ adults and children 12 years of age and over take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours ■ children under 12 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 ■ 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) ■ protect from excessive moisture</p> <p>Inactive ingredients colloidal silicone dioxide, croscarmellose sodium, hypromellose, iron oxide blends, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, titanium dioxide</p> <p>Questions or comments? call toll-free 1-800-633-1610 or www.allegra.com</p>	<p>50094567</p>
---	--	--	-----------------

FOR FDA SUBMISSION ONLY

**ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY**

NDC 41167-4120-4

Allegra[®] Allergy

fexofenadine HCl tablet
180 mg/
antihistamine **24 HOUR**
Indoor and Outdoor Allergies

45 Tablets 180 mg each

Active ingredient (in each tablet)
Fexofenadine HCl 180 mg.....Antihistamine

Purpose
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 ■ **adults and children 12 years of age and over** take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours ■ **children under 12 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** ■ 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) ■ protect from excessive moisture

Inactive ingredients colloidal silicone dioxide, croscarmellose sodium, hydroxypropylcellulose, iron oxide blends, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, titanium dioxide

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

The trade dress of this Allegra[®] package is subject to trademark protection.
Dist. By: Chatter, Inc. (part of the sanofi-aventis Group), Chattanooga, TN 37409-0219 ©2010

50092994

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