Brand Names

Allegra, Allegra Allergy 12 Hour , Allegra Allergy 24 Hour, Allegra Children's Allergy , Allegra Children's Allergy ODT, Allegra Hives, Allegra ODT, Allergy Relief, Children's Allergy

Indication Specific Dosing

For the management of symptoms of perennial allergies, seasonal allergies, or other respiratory allergies, including allergic rhinitis

Oral dosage (tablets)

Adults

60 mg PO twice daily. Alternatively, 180 mg PO once daily.

Children and Adolescents 12 to 17 years

60 mg PO twice daily. Alternatively, 180 mg PO once daily.

Children 6 to 11 years

30 mg PO twice daily.

Oral dosage (orally disintegrating tablets [ODT])

Adults

60 mg PO twice daily; place on the tongue and allow to disintegrate.

Children and Adolescents 12 to 17 years

60 mg PO twice daily; place on the tongue and allow to disintegrate.

Children 6 to 11 years

30 mg PO twice daily; place on the tongue and allow to disintegrate.

Oral dosage (oral suspension containing 30 mg fexofenadine per 5 mL)

Adults, Adolescents, and Children 12 years and older

60 mg PO twice daily.

Children and Adolescents 12 to 17 years

60 mg PO twice daily.

Children 2 to 11 years

30 mg PO twice daily.

For the treatment of uncomplicated skin manifestations of chronic spontaneous urticaria (chronic idiopathic urticaria)

Oral dosage (tablets)

Adults

60 mg PO twice daily. Alternatively, 180 mg PO once daily.

Children and Adolescents 12 to 17 years

60 mg PO twice daily. Alternatively, 180 mg PO once daily.

Children 6 to 11 years

30 mg PO twice daily.

Oral dosage (orally disintegrating tablets [ODT])

Children 6 to 11 years

30 mg PO twice daily; place on tongue and allow to disintegrate.

Oral dosage (oral suspension containing fexofenadine 30 mg per 5 mL)

Children 2 to 11 years

30 mg PO twice daily.

Infants and Children 6 months and up to 2 years

15 mg PO twice daily. Prescription use only in this age group.

Contraindications And Precaution

Drug Interactions

The coadministration of certain medications may lead to harm and require avoidance or therapy modification; review all drug interactions prior to concomitant use of other medications.

Hypersensitivity

This medication is contraindicated in patients with a history of hypersensitivity to it or any of its components. Use fexofenadine with caution in patients with terfenadine hypersensitivity due to the similarity in chemical structure.

renal failure, renal impairment

People with renal impairment, including those with renal failure or receiving dialysis, should consult their care team prior to nonprescription use of fexofenadine. A dosage adjustment is recommended in people with renal impairment or renal failure

phenylketonuria

Fexofenadine oral disintegrating tablets (ODT) contain aspartame, a source of phenylalanine. Use the ODT dosage form with caution in people with phenylketonuria.

children, infants, neonates

Due to the risk for serious adverse reactions, the FDA recommends against administration of over the counter (OTC) cough and cold and allergy products to neonates, infants and children younger than 2 years of age. When administering OTC medications to older pediatric patients, they advise caregivers to read product labels carefully, use caution when administering multiple products to avoid duplication of ingredients, and use only measuring devices specifically designed for use with medications. Care teams should thoroughly assess the use of similar products, both prescription and nonprescription, to avoid duplication of therapy and the potential for inadvertent overdose.

pregnancy

Use of fexofenadine during pregnancy does not appear to be associated with an increased risk of adverse fetal outcomes. Pregnant individuals should consult their care team for a proper diagnosis and for treatment recommendations prior to nonprescription use. Loratadine and oral cetirizine are acceptable antihistamine alternatives based on their excellent safety data and recommendation in multiple guidelines for use to treat allergies and urticaria during pregnancy.

breast-feeding

Fexofenadine is considered to be compatible with breast-feeding due to the likely low levels in human milk and low propensity for sedation. Fexofenadine, a metabolite of terfenadine, is found in human milk only in low amounts based on a limited lactation study with the parent drug. Alternatives may also be considered. Guidelines recommend loratadine or cetirizine at the lowest dose as preferred antihistamines in breast-feeding individuals because they are safe with only low levels found in breast milk.

Pregnancy And Lactation

Use of fexofenadine during pregnancy does not appear to be associated with an increased risk of adverse fetal outcomes. Pregnant individuals should consult their care team for a proper diagnosis and for treatment recommendations prior to nonprescription use. Loratadine and oral cetirizine are acceptable antihistamine alternatives based on their excellent safety data and recommendation in multiple guidelines for use to treat allergies and urticaria during pregnancy.

Interactions

Alogliptin; Pioglitazone: (Minor) Concentrations of fexofenadine may be increased with concomitant use of pioglitazone. The effect of pioglitazone capistration on the systemic exposure of fexofenadine was determined in a drug-drug interaction study. Coadministration of pioglitazone 45 mg once daily with fexofenadine 60 mg twice daily for 7 days resulted in a 30% and 37% increase in fexofenadine AUC and Cmax, respectively. Patients should be monitored for increased side effects from fexofenadine.
Aluminum Hydroxide: (Moderate) Coadministration with antacids (containing aluminum or magnesium) within 15 minutes decreases the AUC and Cmax of fexofenadine by 41% and 43%, respectively. Separate administration is recommended.
Aluminum Hydroxide; Magnesium Carbonate: (Moderate) Coadministration with antacids (containing aluminum or magnesium) within 15 minutes decreases the AUC and Cmax of fexofenadine by 41% and 43%, respectively. Separate administration is

recommended.
Aluminum Hydroxide; Magnesium Hydroxide: (Moderate) Coadministration with antacids (containing aluminum or magnesium) within 15 minutes decreases the AUC and Cmax of fexofenadine by 41% and 43%, respectively. Separate administration is recommended.
Aluminum Hydroxide; Magnesium Hydroxide; Simethicone: (Moderate) Coadministration with antacids (containing aluminum or magnesium) within 15 minutes decreases the AUC and Cmax of fexofenadine by 41% and 43%, respectively. Separate administration is recommended.
Aluminum Hydroxide; Magnesium Trisilicate: (Moderate) Coadministration with antacids (containing aluminum or magnesium) within 15 minutes decreases the AUC and Cmax of fexofenadine by 41% and 43%, respectively. Separate administration is recommended.
Antacids: (Moderate) Coadministration with antacids (containing aluminum or magnesium) within 15 minutes decreases the AUC and Cmax of fexofenadine by 41% and 43%, respectively. Separate administration is recommended.
Aspirin, ASA; Citric Acid; Sodium Bicarbonate: (Major) Co-administration with antacids within 15 minutes decreases the AUC and Cmax of fexofenadine. Separate administration is recommended.
Calcium Carbonate: (Moderate) Co-administration with antacids within 15 minutes decreases the AUC and Cmax of fexofenadine. Separate administration is recommended.
Calcium Carbonate; Famotidine; Magnesium Hydroxide: (Moderate) Co-administration with antacids within 15 minutes decreases the AUC and Cmax of fexofenadine. Separate administration is recommended.
Calcium Carbonate; Magnesium Hydroxide: (Moderate) Co-administration with antacids within 15 minutes decreases the AUC and Cmax of fexofenadine. Separate administration is recommended.
Calcium Carbonate; Magnesium Hydroxide; Simethicone: (Moderate) Co-administration with antacids within 15 minutes decreases the AUC and Cmax of fexofenadine. Separate administration is recommended.
Calcium Carbonate; Simethicone: (Moderate) Co-administration with antacids within 15 minutes decreases the AUC and Cmax of fexofenadine. Separate administration is recommended.
Calcium; Vitamin D: (Moderate) Co-administration with antacids within 15 minutes decreases the AUC and Cmax of fexofenadine. Separate administration is recommended.
Desloratadine: (Minor) Although desloratadine is considered a 'non-sedating' antihistamine, dose-related sedation has been noted. For this reason, it would be prudent to monitor for drowsiness during concurrent use of desloratadine with CNS depressants such as other H1-blockers.

Desloratadine; Pseudoephedrine: (Minor) Although desloratadine is considered a 'non-sedating' antihistamine, dose-related sedation has been noted. For this reason, it would be prudent to monitor for drowsiness during concurrent use of desloratadine with CNS depressants such as other H1-blockers.
Elexacaftor; tezacaftor; ivacaftor: (Moderate) Monitor for fexofenadine-related adverse reactions during coadministration of elexacaftor; tezacaftor; ivacaftor as concurrent use may increase exposure of fexofenadine. Fexofenadine is a substrate for the transporters OATP1B1 and OATP1B3; elexacaftor; tezacaftor; ivacaftor may inhibit uptake of OATP1B1 and OATP1B3.
Eltrombopag: (Moderate) Monitor patients for fexofenadine adverse reactions if coadministered with eltrombopag. Eltrombopag is an inhibitor of the transporter OATP1B1. Drugs that are substrates for this transporter, such as fexofenadine, may exhibit an increase in systemic exposure if coadministered with eltrombopag.
Etravirine: (Moderate) Etravirine is an inhibitor of the efflux transporter P-glycoprotein (PGP). Fexofenadine is a P-glycoprotein substrate. Increased concentrations of fexofenadine may occur if it is coadministered with etravirine; exercise caution.
Grapefruit juice: (Major) Fruit juices such as grapefruit juice, orange juice, and apple juice may reduce the bioavailability, systemic exposure, and clinical efficacy of fexofenadine. Patients should avoid drinking fruit juice within 4 hours before and 1 to 2 hours after taking fexofenadine; tablets and capsules should be consumed with water, not juice. Many fruit juices are organic anion transporting peptide (OATP) 1A2 and/or OATP2B1 inhibitors. OATP-mediated transport facilitates the intestinal absorption of fexofenadine. It is estimated that the bioavailability of fexofenadine is decreased by 36% when coadministered with grapefruit or orange juice. Apple juice, orange juice, and grapefruit juice have been reported to decrease the AUC and Cmax of fexofenadine by up to 70%.
Heparin: (Minor) Antihistamines may partially counteract the anticoagulant actions of heparin, according to the product labels. However, this interaction is not likely of clinical significance since heparin therapy is adjusted to the partial thromboplastin time (aPTT) and other clinical parameters of the patient.
Ketoconazole: (Minor) Ketoconazole may inhibit the metabolism of fexofenadine via its effects on the CYP3A4 isozyme of the cytochrome P-450 microsomal enzyme system.
Levoketoconazole: (Minor) Ketoconazole may inhibit the metabolism of fexofenadine via its effects on the CYP3A4 isozyme of the cytochrome P-450 microsomal enzyme system.
Lopinavir; Ritonavir: (Moderate) Monitor for fexofenadine-related adverse reactions during concurrent administration with lopinavir as use of these drugs together may increase exposure of fexofenadine. Fexofenadine is a substrate of the organic anion transporting peptide (OATP1B1); lopinavir inhibits OATP1B1.
Loratadine: (Minor) Although loratadine is considered a 'non-sedating' antihistamine, dose-related sedation has been noted. For this reason, it would be prudent to monitor for drowsiness during concurrent use of loratadine with CNS depressants such as other

H1-blockers.
Loratadine; Pseudoephedrine: (Minor) Although loratadine is considered a 'non-sedating' antihistamine, dose-related sedation has been noted. For this reason, it would be prudent to monitor for drowsiness during concurrent use of loratadine with CNS depressants such as other H1-blockers.
Magnesium Hydroxide: (Moderate) Coadministration with antacids (containing aluminum or magnesium) within 15 minutes decreases the AUC and Cmax of fexofenadine by 41% and 43%, respectively. Separate administration is recommended.
Magnesium Salts: (Moderate) Coadministration with antacids (containing aluminum or magnesium) within 15 minutes decreases the AUC and Cmax of fexofenadine by 41% and 43%, respectively. Separate administration is recommended.
Omeprazole; Sodium Bicarbonate: (Major) Co-administration with antacids within 15 minutes decreases the AUC and Cmax of fexofenadine. Separate administration is recommended.
Pioglitazone: (Minor) Concentrations of fexofenadine may be increased with concomitant use of pioglitazone. The effect of pioglitazone capistration on the systemic exposure of fexofenadine was determined in a drug-drug interaction study. Coadministration of pioglitazone 45 mg once daily with fexofenadine 60 mg twice daily for 7 days resulted in a 30% and 37% increase in fexofenadine AUC and Cmax, respectively. Patients should be monitored for increased side effects from fexofenadine.
Pioglitazone; Glimepiride: (Minor) Concentrations of fexofenadine may be increased with concomitant use of pioglitazone. The effect of pioglitazone capistration on the systemic exposure of fexofenadine was determined in a drug-drug interaction study. Coadministration of pioglitazone 45 mg once daily with fexofenadine 60 mg twice daily for 7 days resulted in a 30% and 37% increase in fexofenadine AUC and Cmax, respectively. Patients should be monitored for increased side effects from fexofenadine.
Pioglitazone; metFORMIN: (Minor) Concentrations of fexofenadine may be increased with concomitant use of pioglitazone. The effect of pioglitazone capistration on the systemic exposure of fexofenadine was determined in a drug-drug interaction study. Coadministration of pioglitazone 45 mg once daily with fexofenadine 60 mg twice daily for 7 days resulted in a 30% and 37% increase in fexofenadine AUC and Cmax, respectively. Patients should be monitored for increased side effects from fexofenadine.
Posaconazole: (Moderate) Posaconazole and fexofenadine should be coadministered with caution due to a potential for altered plasma concentrations of both drugs. Both fexofenadine and posaconazole are substrates of the drug efflux protein, P-glycoprotein, which when administered together may increase the absorption or decrease the clearance of the other drug. This interaction may cause alterations in the plasma concentrations of both posaconazole and fexofenadine, ultimately resulting in an increased risk of adverse events.
rifAMPin: (Minor) Rifampin may decrease plasma concentrations of fexofenadine and

potentially reduce its antihistaminic effects. Although the therapeutic range of fexofenadine is broad, monitor for potential decreased therapeutic effects of fexofenadine if rifampin is initiated.
Sincalide: (Moderate) Sincalide-induced gallbladder ejection fraction may be affected by concurrent medications, including H1-blockers. False study results are possible; thorough patient history is important in the interpretation of procedure results.
Sodium Bicarbonate: (Major) Co-administration with antacids within 15 minutes decreases the AUC and Cmax of fexofenadine. Separate administration is recommended.
St. John's Wort, Hypericum perforatum: (Minor) St. John's Wort may increase, decrease, or not change the plasma concentrations and AUC of fexofenadine. The mechanisms proposed have included CYP3A4 induction and/or altered P-glycoprotein efflux transport of fexofenadine. The clinical importance of this theoretical interaction has not been established; further study is needed.

Adverse Reaction

General Information

Fexofenadine is a metabolite of terfenadine. Terfenadine has been associated with QT prolongation and ventricular tachycardias (torsade de pointes) and was withdrawn from the U.S. market after ten years of post-marketing experience. Pre-marketing trials with fexofenadine in greater than 900 patients demonstrated no significant prolongation of the QT interval at doses of 60—240 mg PO twice daily. One case report documented ventricular tachycardia associated with QT prolongation during therapy with fexofenadine in a patient with a history of prolonged QT interval. No cases of cardiac arrhythmias are reported in the fexofenadine or Allegra-D product information. No QT prolongation was evident with the maximum fexofenadine dosage studied (400 mg PO twice daily for seven days in healthy subjects).

back pain, cough, diarrhea, dizziness, dysmenorrhea, dyspepsia, fatigue, fever, headache, infection, myalgia, pharyngitis, rhinorrhea, vomiting

The most common adverse reactions associated with fexofenadine therapy include headache (4.8—10.3%) and vomiting (4.2—12%). Other adverse reactions included back pain (2.1—2.5%), cough (1.9—4%), diarrhea (2.8—3.7%), dizziness (2.1%), dysmenorrhea (1.5%), dyspepsia (4.7%), somnolence or fatigue (0.7—2.8%), fever or pyrexia (1.9—4.5%), myalgia (2.6%), naso-pharyngitis (2.4%), rhinorrhea (0.9—2.1%), accidental injury (2.9%), unspecified pain (2.4%), and extremity pain (2.1%). Infections were also reported during fexofenadine use, including upper respiratory tract infection (0.9—4.3%) and otitis

media (2.4—3.8%). Adverse reactions reported in greater than 2% of patients in a placebo controlled pediatric study (age 6—11 years) included headache (7.2%), accidental injury (2.9%), cough (3.8%), fever (2.4%), otitis media (2.4%), pain (unspecified) (2.4%), and upper respiratory tract infection (4.3%). Other adverse events which have been reported in clinical trials of patients 12 years of age and older include dizziness (2.1%), myalgia (2.6%), pharyngitis (nasal) (2.4%), upper respiratory tract infection (2.4%), dyspepsia (4.7%), headache (4.8%), back pain (2.1%) and unspecified pain in extremity (2.1%). Adverse effects reported with oral suspension or capsule content administration in greater than 2% of patients in placebo-controlled pediatric studies (age 6 months to 5 years) included vomiting (5.8%), pyrexia (fever) (3.9%), cough (3.6%), otitis media (3.6%), diarrhea (3%), rhinorrhea (1.9%), upper respiratory tract infections (1.9%), and somnolence or fatigue (1.1%). Pyrexia (fever) and upper respiratory infection occurred less frequently in the fexofenadine groups than the placebo groups. Vomiting was reported in 12% of subjects receiving fexofenadine 30 mg/day and 4.2% of those receiving 60 mg/day, with an incidence of 8.6% in the placebo group.

anaphylactoid reactions, angioedema, chest pain (unspecified), dyspnea, flushing, insomnia, paranoia, pruritus, rash, restlessness, urticaria

Events that have been reported during controlled clinical trials involving seasonal allergic rhinitis and chronic spontaneous urticaria patients with frequencies less than 1%, similar to placebo, and have rarely been reported during post-marketing surveillance of fexofenadine include: insomnia, nervousness (restlessness), and sleep disorders or paranoia. In rare cases, rash (unspecified), urticaria, pruritus and hypersensitivity reactions (anaphylactoid reactions) with manifestations such as angioedema, chest tightness/chest pain (unspecified), dyspnea, flushing and systemic anaphylaxis have been reported.

Description

Fexofenadine is a non-sedating antihistamine (H1-receptor antagonist). It is the active metabolite of another H1-antagonist, terfenadine. Unlike terfenadine, fexofenadine does not generally cause QT prolongation when given in doses up to 800 mg/day or when administered concomitantly with ketoconazole or erythromycin. However, one case report documented ventricular tachycardia associated with QT prolongation during fexofenadine therapy in a patient with a history of prolonged QT interval. Fexofenadine was first FDA approved in July 1996 for the treatment of seasonal allergic rhinitis; subsequent approval was granted in February 2000 for a once-daily product and for the treatment of chronic spontaneous urticaria. Other formulations were similarly approved including an oral liquid in October 2006 and an orally disintegrating tablet in July 2007. In

January 2011, the FDA approved the over-the-counter sale of fexofenadine in the same formulations, strengths, and indications as available by prescription, with the exception that treatment of urticaria in certain pediatric patients.

Mechanism Of Action

Fexofenadine is an antihistamine with selective H1-receptor antagonist activity. Similar to other H1-blockers, fexofenadine does not prevent the release of histamine as do cromolyn and nedocromil, but competes with free histamine for binding at the H1-receptor. This competitive antagonism blocks the effects of histamine on H1-receptors in the GI tract, uterus, large blood vessels, and bronchial smooth muscle. Blockade of H1-receptors also suppresses the formation of edema, flare, and pruritus that result from histaminic activity. At higher concentrations, H1-receptor antagonism becomes relatively irreversible. Fexofenadine does not cross the blood-brain barrier and does not exert anticholinergic or alpha-1-antagonist effects in animal studies. In humans, CNS depression is minimal compared with first-generation H1-antagonists. Although fexofenadine is a metabolite of terfenadine which has been associated with QT prolongation and ventricular tachycardias (torsades de pointes), pre-marketing trials with fexofenadine demonstrated no significant prolongation of the QT interval; doses up to 800 mg/day have been studied.

Pharmacokinetics

Fexofenadine is administered orally. The onset of antihistamine effectiveness (evaluated by wheal and flare studies) is about 1 hour and persists for up to 12 hours. Protein binding ranges from 60% to 70%; fexofenadine is primarily bound to albumin and alpha-1-acid glycoprotein. Based on radiolabeled studies, approximately 80% and 11% of a dose was recovered in the feces and urine, respectively. Approximately 5% of the total administered dose is metabolized. Because the absolute bioavailability has not been determined, it is unknown if the fecal component represents unabsorbed drug or biliary excretion of the drug. Therefore, it is unknown if either renal excretion and/or metabolism plays a significant role in systemic drug elimination. The mean elimination half-life is approximately 14.4 hours in normal volunteers receiving 60 mg twice daily.

Affected Cytochrome P450 (CYP450) enzymes and drug transporters: P-glycoprotein (P-gp) and OATP
Fexofenadine is a substrate for P-glycoprotein (P-gp) and organic anion transporting peptide (OATP) transport.

Route-Specific Pharmacokinetics

- **Oral Route**

Fexofenadine is rapidly absorbed. The absolute bioavailability of fexofenadine is unknown. The mean time to maximum plasma concentrations (Tmax) following oral administration with conventional tablets, capsule or oral solution is 2 to 3 hours and 1 hour, respectively. The Tmax of the orally disintegrating tablet (ODT) formulation is 2 hours post-dose. Administration of the ODT formulation with a high fat-meal decreases the AUC and maximum concentration (Cmax) by about 40% and 60%, respectively, and Tmax is delayed by 2 hours. When the conventional tablet or capsule is given with a high fat meal, the AUC and Cmax are decreased by approximately 20%. Mixing capsule contents with applesauce has no significant effect on the pharmacokinetic parameters. Administration of the oral suspension and a high fat meal decreases the exposure (AUC) and Cmax by approximately 30% and 47% respectively. The tablets, capsule, and oral suspension may be given with food. The fexofenadine ODT should be taken on an empty stomach, but it may be taken with water. Fexofenadine oral suspension is bioequivalent to fexofenadine tablets on a mg per mg basis.

- **Hepatic Impairment**

The pharmacokinetics of fexofenadine are not altered by hepatic disease. The pharmacokinetics of fexofenadine hydrochloride in adult patients with hepatic disease did not differ substantially from that observed in healthy subjects.

- **Renal Impairment**

The pharmacokinetics of fexofenadine are altered by renal disease. Peak plasma concentrations were 87% and 111% greater in patients with mild (CrCl 41 to 80 mL/minute) to severe (CrCl 11 to 40 mL/minute) renal impairment, respectively. Mean elimination half-lives were 59% and 72% longer, respectively, than in normal volunteers. Peak plasma concentrations in dialysis patients (CrCl 10 mL/minute or less) were 82% greater and half-life was 31% longer than in normal volunteers. The effect of hemodialysis on the removal of fexofenadine is unknown. Hemodialysis did not effectively remove fexofenadine from blood (up to 1.7% removed) following terfenadine oral administration.

- **Pediatrics**

Infants and Children

Fexofenadine, when given in age appropriate doses in infants and children, produces comparable plasma exposure to that seen in adults receiving a 60 mg dose. A population pharmacokinetic analysis was performed using data from 90 treatment exposures in children (6 months to 12 years) and 269 treatment exposures from adults. Estimated oral clearances were on average 36% and 44% lower in children 2 to 5 years and 6 to 12 years, respectively, compared to adults. In a double-blind, two-way crossover study, 14 children (mean age 9.8 +/- 1.8 years) received a single dose of fexofenadine 30 mg and 60 mg 1 week apart. The following mean pharmacokinetic parameters were

calculated for the 30 mg dose: Volume of distribution (Vd) = 5.4 +/- 0.7 L/kg, clearance (CL) = 14.4 +/- 2 mL/kg/minute, and terminal elimination half-life (T1/2) = 18.3 +/- 2 hours. The following parameters were calculated for the 60 mg dose: Vd = 5.8 +/- 0.7 L/kg, CL = 18.4 +/- 2.4 mL/kg/minute, and terminal elimination half-life (T1/2) = 17.6 +/- 1 hours.

- **Geriatric**

The pharmacokinetics of fexofenadine is altered by age. In older subjects greater than 65 years old, peak plasma levels of fexofenadine were 99% greater than those observed in younger adult subjects less than 65 years old. Mean elimination half-lives were similar to those observed in younger subjects.

- **Gender Differences**

The pharmacokinetics of fexofenadine is not altered by gender. No clinically significant gender-related differences were observed in the pharmacokinetics of fexofenadine.

Administration

For storage information, see the specific product information within the How Supplied section.

Oral Administration

Avoid administration with fruit juice, including grapefruit, orange, and apple juice, before or after fexofenadine administration to avoid a potential reduction in bioavailability.
Do not administer at the same time as aluminum or magnesium antacids.

Oral Solid Formulations

Tablets or capsules
Administer with a glass of water.

Orally disintegrating tablets (ODT)
Do not remove from original blister package until the time of administration.
Dissolve ODT on the tongue then swallow with or without water; do not chew.
Administer ODT on an empty stomach.

Oral Liquid Formulations

Oral suspension
Shake well prior to each use.
Measure dosage using a calibrated oral measuring device to ensure accurate dosage.

Maximum Dosage Limits

- **Adults**
  180 mg/day PO if given once daily; 120 mg/day if given in 2 divided doses.
- **Geriatric**
  180 mg/day PO if given once daily; 120 mg/day if given in 2 divided doses.
- **Adolescents**
  180 mg/day PO if given once daily; 120 mg/day if given in 2 divided doses.
- **Children**
  12 years: 180 mg/day PO if given once daily; 120 mg/day if given in 2 divided doses.
  2 to 11 years: 60 mg/day PO, given in 2 divided doses.
  Less than 2 years: Safety and efficacy have not been established for nonprescription use. If by prescription, do not exceed 30 mg/day PO.
- **Infants**
  Safety and efficacy have not been established for nonprescription use. If by prescription, do not exceed 30 mg/day PO.
- **Neonates**
  Safety and efficacy have not been established.

Dosage Forms

- Allegra 180mg Tablet
- ALLEGRA ALLERGY 12 Hour 60mg Tablet
- Allegra Allergy 12 Hour Tablet
- Allegra Allergy 24 Hour 180mg Tablet
- ALLEGRA ALLERGY 24 Hour 180mg Tablet
- Allegra Allergy 24 Hour Gelcap Tablet
- Allegra Allergy 24 Hour Tablet
- Allegra Children's Allergy 30mg Orally Disintegrating Tablet
- Allegra Children's Allergy 30mg Orally Disintegrating Tablet (Orange Cream)
- Allegra Children's Allergy 30mg/5ml Suspension
- Allegra Hives 24 Hour 180mg Tablet
- Allegra-D 12 Hour 60mg-120mg Extended-Release Tablet
- Allegra-D 12 Hour Allergy & Congestion 60mg-120mg Extended-Release Tablet
- Allegra-D 12 Hour Allergy & Congestion Extended-Release Tablet
- Allegra-D 24 Hour 180mg-240mg Extended-Release Tablet
- Allegra-D 24 Hour Allergy & Congestion Extended-Release Tablet

- Allergy Relief 12 Hour 60mg Tablet
- Allergy Relief 24 Hour 180mg Tablet
- Allergy Relief 24 Hour Relief 180mg Tablet
- Allergy Relief 24 Hour Relief 180mg Tablet
- Children's Allergy 30mg/5mL Suspension (Berry)
- CVS Allergy & Hives Relief 24 Hour 180mg Tablet
- CVS Allergy Relief 12 Hour 60mg Tablet
- CVS Allergy Relief 24 Hour 180mg Tablet
- CVS Allergy Relief D 12 Hour 60mg-120mg Extended-Release Tablet
- CVS Allergy Relief D 12 Hour Extended-Release Tablet
- CVS Allergy Relief D 24 Hour Extended-Release Tablet
- CVS Allergy Relief D24 180mg-240mg Extended-Release Tablet
- CVS Children's Allergy Relief 30mg/5mL Suspension (Berry)
- Equate Allergy Relief 24 Hour 180mg Tablet
- Equate Allergy Relief Non Drowsy 180mg Tablet
- Equate Allergy Relief Non Drowsy 180mg Tablet
- Equate Allergy Relief Non-Drowsy 24 Hour 180mg Caplet
- Equate Children's Allergy Relief 30mg/5mL Suspension (Berry)
- Equate Non-Drowsy 24 Hour Allergy Relief 180mg Caplet
- Equate Non-Drowsy Allergy Relief D 12 Hour 60mg-120mg Extended-Release Tablet
- Equate Non-Drowsy Allergy Relief D 12 Hour 60mg-120mg Extended-Release Tablets
- Fexofenadine Hydrochloride 180mg Oral tablet
- Fexofenadine Hydrochloride 180mg, Pseudoephedrine Hydrochloride 240mg Oral tablet, extended release 24 hour
- Fexofenadine Hydrochloride 30mg Oral tablet
- Fexofenadine Hydrochloride 30mg/5mL Oral suspension
- Fexofenadine Hydrochloride 60mg Oral tablet
- Fexofenadine Hydrochloride 60mg, Pseudoephedrine Hydrochloride 120mg Oral tablet, extended release 12 hour
- Fexofenadine Hydrochloride Bulk powder
- Foster & Thrive Allergy Relief 12 Hour 60mg Tablet
- Foster & Thrive Allergy Relief 180mg Tablet
- Foster & Thrive Allergy Relief 24 Hour 180mg Tablet
- GNP Allergy Relief 180mg Tablet
- GNP Allergy Relief 180mg Tablet
- GNP Allergy Relief 24 Hour 180mg Tablet
- GNP Fexofenadine Hydrochloride 24 Hour Antihistamine180mg Tablet
- GNP Fexofenadine Hydrochloride/Pseudoephedrine Hydrochloride 60mg-120mg 12 Hour Extended-Release Tablet

- GNP Fexofenadine Hydrochloride/Pseudoephedrine Hydrochloride 60mg-120mg 12 Hour Extended-Release Tablet
- GoodSense Aller-Ease 12 Hour 60mg Tablet
- GoodSense Aller-Ease 24 Hour 180mg Tablet
- HEB Allergy Relief 24 Hour 180mg Tablet
- HEB Allergy Relief 60mg Tablet
- Kirkland ALLER-FEX 24 Hour 180mg Tablet
- Leader 24 Hour Allergy & Congestion Relief 180mg-240mg Extended-Release Tablet
- Leader 24HR Allergy Relief 180mg Tablet
- Leader Aller-Ease 180mg Tablet
- Leader Allergy Relief 12 hour 60mg Tablet
- Leader Allergy Relief 180mg Tablet
- Leader Allergy Relief 24HR 180mg Tablet
- Picnic Allergy Relief 24 Hour 180mg Tablet
- Premier Value Allergy Relief 180mg Tablet
- Premier Value Children's Allergy 30mg/5ml Suspension (Berry)
- Premier Value Fexofenadine Hydrochloride 180mg Tablet
- Premier Value Fexofenadine Hydrochloride 180mg Tablet
- Publix Allergy Relief 180mg Tablet
- Quality Choice Allergy Relief 180mg Tablet
- Quality Choice Allergy Relief 60mg Tablet
- Quality Choice Fexofenadine Hydrochloride 24 Hour Relief 180mg Tablet
- RITE AID Allergy Relief 24 Hour 180mg Tablet
- Top Care Fexofenadine Hydrochloride 180mg Tablet
- Top Care Fexofenadine Hydrochloride 60mg Tablet
- TopCare Allergy Relief 24 Hour 180mg Tablet
- Wal-Fex 24 Hour Allergy 180mg Tablet
- Wal-Fex Children's 30mg/5ml Suspension
- Walgreens Allergy Relief 24 Hour 180mg Tablet
- Walgreens Allergy Relief D12 60mg-120mg Extended-Release Tablets
- Walgreens Allergy Relief Non-Drowsy 24 Hour 180mg Tablet
- Walgreens Non-Drowsy Allergy Relief D24 180mg-240mg Extended-Release Tablet

Dosage Adjustment Guidelines

Hepatic Impairment

No dosage adjustment is recommended.

Renal Impairment

Dosage adjustments are recommended according to age and the degree of renal impairment:
Adults
CrCl 80 mL/minute/1.73 m2 or less: Reduce starting dosage to 60 mg PO once daily.
Children and Adolescents 12 to 17 years:
CrCl 80 mL/minute/1.73 m2 or less: Reduce starting dosage to 60 mg PO once daily. One resource recommends 30 mg PO once daily if the CrCl is less than 10 mL/minute/1.73 m2 in pediatric patients.
Children 2 to 11 years:
CrCl 80 mL/minute/1.73 m2 or less: Reduce starting dosage to 30 mg PO once daily.
Infants and Children 6 months to less than 2 years:
No renal impairment data are available; not recommended.

Intermittent hemodialysis
See dosage for renal impairment. Hemodialysis is not expected to appreciably remove fexofenadine.
