Brand Names

Alavert, Alavert Children's, Allergy Relief, Claritin, Claritin 24 Hour, Claritin Chewable, Claritin Hives Relief, Claritin Liqui-Gel, Claritin RediTabs, Clear-Atadine , Dimetapp Children's Non-Drowsy Allergy, QlearQuil All Day & All Night Allergy Relief, Quality Choice Allergy Relief Non-Drowsy, Tavist ND

Indication Specific Dosing

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

Oral dosage (tablets or liquid-filled capsules)

Adults

10 mg PO once daily. Max: 10 mg/day.

Children and Adolescents 6 to 17 years

10 mg PO once daily. Max: 10 mg/day.

Oral dosage (orally disintegrating tablets)

Adults

5 mg PO twice daily or 10 mg PO once daily. Tablet disintegrates with or without water. Max: 10 mg/day.

Children and Adolescents 6 to 17 years

5 mg PO twice daily or 10 mg PO once daily. Tablet disintegrates with or without water. Max: 10 mg/day.

Oral dosage (chewable tablets)

Adults

10 mg PO once daily. Max: 10 mg/day.

Children and Adolescents 6 to 17 years

10 mg PO once daily. Max: 10 mg/day.

Children 2 to 5 years

5 mg PO once daily. Max: 5 mg/day.

Oral dosage (oral syrup or solution)

Adults

10 mg PO once daily. Max: 10 mg/day.

Children and Adolescents 6 to 17 years

10 mg PO once daily. Max: 10 mg/day.

Children 2 to 5 years

5 mg PO once daily. Max: 5 mg/day.

For the management of symptoms of chronic spontaneous urticaria (e.g., relief of pruritus, reduction in the size and number of hives)

Oral dosage (tablets or liquid-filled capsules)

Adults

10 mg PO once daily. Max: 10 mg/day.

Children and Adolescents 6 to 17 years

10 mg PO once daily. Max: 10 mg/day.

Oral dosage (orally disintegrating tablets)

Adults

5 mg PO twice daily or 10 mg once daily. Tablet disintegrates with or without water. Max: 10 mg/day.

Children and Adolescents 6 to 17 years

5 mg PO twice daily or 10 mg once daily. Tablet disintegrates with or without water. Max: 10 mg/day.

Oral dosage (chewable tablets)

Adults

10 mg PO once daily. Max: 10 mg/day.

Children and Adolescents 6 to 17 years

10 mg PO once daily. Max: 10 mg/day.

Children 2 to 5 years

5 mg PO once daily. Max: 5 mg/day.

Oral dosage (oral syrup or solution)

Adults

10 mg PO once daily. Max: 10 mg/day.

Children and Adolescents 6 to 17 years

10 mg PO once daily. Max: 10 mg/day.

Children 2 to 5 years

5 mg PO once daily. Max: 5 mg/day.

For adjunctive exercise-induced bronchospasm prophylaxis† in patients with allergies

Oral dosage

Adults

10 mg PO once daily. Better allergy control can lead to better asthma control. Recommended for those with exercise-induced bronchospasm (EIB) and allergies with continued symptoms despite using inhaled EIB prophylaxis. Antihistamines should not be used in asthma patients who do not have allergies.

Children and Adolescents 6 to 17 years

10 mg PO once daily. Better allergy control can lead to better asthma control. Recommended for those with exercise-induced bronchospasm (EIB) and allergies with continued symptoms despite using inhaled EIB prophylaxis. Antihistamines should not be used in asthma patients who do not have allergies.

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. Do not use in people with a history of allergy to desloratadine, which is a metabolite of loratadine.

hepatic failure

People with hepatic failure or impairment should ask their care team before nonprescription use of loratadine since it is extensively metabolized in the liver. A reduced initial dosage of loratadine is recommended in people with hepatic impairment.

renal failure, renal impairment

People with renal impairment or renal failure should ask their care team before nonprescription use of loratadine.. A reduced initial dosage of loratadine is recommended for people with renal impairment with a creatinine clearance less than 30 mL/minute.

phenylketonuria

Some formulations of loratadine (e.g., chewable tablets, and orally disintegrating tablets or ODTs) contain aspartame, which is a source of phenylalanine. Use these dosage forms with caution in patients 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

No teratogenic or mutagenic effects were observed in animal studies of loratadine use during pregnancy. Pregnant individuals should see their health care professional for a proper diagnosis and for treatment recommendations. Loratadine and cetirizine are acceptable antihistamine alternatives based on their excellent safety data and recommendation in multiple guidelines for use during pregnancy.

breast-feeding

Loratadine is considered compatible with breast-feeding because of its lack of sedation and low milk concentrations. Guidelines also recommend loratadine as a preferred antihistamine in breast-feeding individuals. In one study, a single loratadine dose of 40 mg (4 times the usual dose) was administered to 6 lactating women. Average loratadine peak milk concentrations, 2 hours after administration, were 29.2 mcg/L (range 20.4 to 39 mcg/L); average desloratadine peak milk concentrations, 5.3 hours after loratadine administration, were 16 mcg/L (range 9 to 29.6 mcg/L). The total amount excreted in milk over 48 hours was 11.7 mcg of loratadine and desloratadine. The calculated average and maximum expected exposures of loratadine and desloratadine in milk were 0.46% and 1.1% of the maternal weight-adjusted dose, respectively, after the 40 mg dose. Approximately 3 mcg would be expected to be excreted in the milk with a 10 mg dose.

Pregnancy And Lactation

No teratogenic or mutagenic effects were observed in animal studies of loratadine use during pregnancy. Pregnant individuals should see their health care professional for a proper diagnosis and for treatment recommendations. Loratadine and cetirizine are acceptable antihistamine alternatives based on their excellent safety data and recommendation in multiple guidelines for use during pregnancy.

Interactions

Acetaminophen; Aspirin; diphenhydrAMINE: (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.
Acetaminophen; Caffeine; Pyrilamine: (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.
Acetaminophen; Chlorpheniramine: (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.
Acetaminophen; Chlorpheniramine; Dextromethorphan: (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.
Acetaminophen; Chlorpheniramine; Dextromethorphan; Phenylephrine: (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.
Acetaminophen; Chlorpheniramine; Dextromethorphan; 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.
Acetaminophen; Chlorpheniramine; Phenylephrine : (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.
Acetaminophen; Dextromethorphan; Doxylamine: (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.
Acetaminophen; diphenhydrAMINE: (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.
Acetaminophen; Pamabrom; Pyrilamine: (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.

Brompheniramine: (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.
Brompheniramine; Dextromethorphan; Phenylephrine: (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.
Brompheniramine; Phenylephrine: (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.
Brompheniramine; 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.
Brompheniramine; Pseudoephedrine; Dextromethorphan: (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.
Carbinoxamine: (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.
Cetirizine: (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.
Cetirizine; 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.
Chlophedianol; Dexbrompheniramine: (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.
Chlophedianol; Dexchlorpheniramine; 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.

Chlorcyclizine: (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.
Chlorpheniramine: (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.
Chlorpheniramine; Codeine: (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.
Chlorpheniramine; Dextromethorphan: (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.
Chlorpheniramine; Dextromethorphan; Phenylephrine: (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.
Chlorpheniramine; Dextromethorphan; 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.
Chlorpheniramine; HYDROcodone: (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.
Chlorpheniramine; Ibuprofen; 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.
Chlorpheniramine; Phenylephrine: (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.
Chlorpheniramine; 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.

Clemastine: (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.
Codeine; Dexbrompheniramine: (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.
Cyproheptadine: (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.
Desloratadine: (Major) Desloratadine is the active metabolite of Loratadine. These 2 drugs should not be given at the same time due to the duplication of therapy and the resultant increase in desloratadine concentrations, which may lead to increased CNS or anticholinergic effects.
Desloratadine; Pseudoephedrine: (Major) Desloratadine is the active metabolite of Loratadine. These 2 drugs should not be given at the same time due to the duplication of therapy and the resultant increase in desloratadine concentrations, which may lead to increased CNS or anticholinergic effects.
Dexbrompheniramine: (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.
Dexbrompheniramine; Dextromethorphan; Phenylephrine: (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.
Dexbrompheniramine; 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.
Dexchlorpheniramine: (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.
Dexchlorpheniramine; Dextromethorphan; 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.

Dextromethorphan; diphenhydrAMINE; Phenylephrine: (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.
dimenhyDRINATE: (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.
diphenhydrAMINE: (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.
diphenhydrAMINE; Ibuprofen: (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.
diphenhydrAMINE; Naproxen: (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.
diphenhydrAMINE; Phenylephrine: (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.
Doxylamine: (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.
Doxylamine; Pyridoxine: (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.
Fexofenadine: (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.
Fexofenadine; 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.

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.
hydrOXYzine: (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.
Levocetirizine: (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.
Meclizine: (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.
Pseudoephedrine; Triprolidine: (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.
Sedating H1-blockers: (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.
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.
Triprolidine: (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.

Adverse Reaction

arthralgia, asthenia, back pain, dizziness, drowsiness, fatigue, headache, hyperhidrosis, hypertonia, hypoesthesia, migraine, muscle cramps, myalgia, paresthesias, seizures, tremor, vertigo

Similar to other low-sedating antihistamines, CNS side effects from loratadine reported in controlled trials at incidences greater than with placebo in adults and pediatric

patients 12 years and older include headache (12%), somnolence/drowsiness (8%) and fatigue (4%). Uncommon adverse effects such as dizziness, hypoesthesia, hyperhidrosis, tremor, vertigo, asthenia, dysphonia, hypertonia, malaise, migraine, muscle cramps (legs), paresthesias, arthralgia, myalgia, and back pain have been reported in at least one adult or pediatric patient receiving loratadine during clinical trials. Nervousness (4%), dysphonia (2%), fatigue (3%), malaise (2%) and hyperkinesis (3%) have been reported in placebo-controlled trials in children 6 to 12 years of age at incidences greater than with placebo. Fatigue occurred in 2% to 3% of young children (2 to 5 years) treated with loratadine. Seizures have rarely been reported during postmarketing experience (patient ages unspecified).

abdominal pain, anorexia, appetite stimulation, constipation, diarrhea, dysgeusia, dyspepsia, flatulence, gastritis, hiccups, nausea, polydipsia, vomiting, weight gain

Gastrointestinal adverse reactions reported with loratadine included diarrhea in 2% to 3% of young children (2 to 5 years) and abdominal pain (2%) in children 6 to 12 years old during clinical trials at rates higher than with placebo. In addition, the following GI adverse events have been reported in at least one adult or pediatric patient receiving loratadine during clinical trials: dysgeusia, anorexia, constipation, diarrhea, dyspepsia, flatulence, gastritis, hiccups, appetite stimulation, loose stools, weight gain, polydipsia, nausea, vomiting.

chest pain (unspecified), hypertension, hypotension, palpitations, peripheral edema, sinus tachycardia, supraventricular tachycardia (SVT), syncope

Cardiovascular adverse events may rarely occur during loratadine therapy at usual dosages. Hypertension, hypotension, palpitations, supraventricular tachycardia (SVT), syncope, sinus tachycardia, and chest pain (unspecified) have been reported in at least one adult or pediatric patient receiving loratadine during clinical trials. Peripheral edema has been reported during postmarketing experience. Palpitations have been reported in children with overdoses of more than 10 mg of loratadine. In a human study in which doses 4 times the clinical dose were administered to adults for up to 90 days, loratadine did not cause clinically significant changes in the QTc interval. The manufacturer reports that in a single, rising-dose study in which doses up to 160 mg (16 times the clinical dose) were studied in adults, loratadine did not cause any clinically significant changes in the QTc interval.

bronchospasm, dyspnea, epistaxis, hemoptysis, laryngitis, nasal dryness, otalgia, pharyngitis, sinusitis, stomatitis, tinnitus, wheezing, xerostomia

Xerostomia (3% vs. 2% placebo) was reported in adult and pediatric patients 12 years and older during clinical trials of loratadine. Pharyngitis, epistaxis, otalgia, stomatitis, influenza-like symptoms, and tooth disorder were reported in 2% to 3% of young children 2 to 5 years of age receiving loratadine during clinical trials. Wheezing (4% vs. 2% placebo) was reported in children 6 to 12 years of age. Adverse effects of the mouth, nose, and throat including altered salivation, bronchitis, bronchospasm, dyspnea, hemoptysis, laryngitis, nasal dryness, sinusitis, otalgia, and tinnitus were reported in at least one adult or pediatric patient receiving loratadine during clinical trials.

chills, cough, fever, infection, sneezing

Respiratory adverse reactions reported with loratadine during clinical trials included viral infection (2% to 3%) in children 2 to 5 years and upper respiratory infection (2%) in pediatric patients 6 to 12 years. Cough, chills, fever, and sneezing were reported in at least one adult or pediatric patient receiving loratadine during clinical trials.

amnesia, anxiety, confusion, depression, insomnia, irritability, libido decrease, paranoia

Amnesia, anxiety, confusion, depression, impaired concentration, insomnia, irritability, paranoia, and libido decrease have been reported in at least one adult or pediatric patient in loratadine clinical trials.

breast enlargement, dysmenorrhea, impotence (erectile dysfunction), mastalgia, menorrhagia, vaginitis

Reproductive organ adverse effects including mastalgia, dysmenorrhea, menorrhagia, vaginitis, and impotence (erectile dysfunction) were reported in at least one adult or pediatric patient in loratadine clinical trials. In addition, breast enlargement has been reported during postmarketing experience.

alopecia, anaphylactoid reactions, angioedema, erythema multiforme, flushing, photosensitivity, pruritus, purpura, rash, urticaria, xerosis

Hypersensitivity reactions including anaphylaxis/anaphylactoid reactions, erythema multiforme, and alopecia have been rarely reported with postmarketing loratadine use. During clinical trials, rash (unspecified) was reported in 2% to 3% of children 2 to 5 years of age. Hypersensitivity or dermatologic reactions reported in at least one adult or pediatric patient during clinical trials include angioedema/angioneurotic edema, dermatitis, dry hair, xerosis, flushing, photosensitivity, pruritus, purpura, and urticaria.

urinary incontinence, urinary retention, urine discoloration

Altered micturition, urine discoloration, urinary incontinence, and urinary retention have been reported in at least one adult or pediatric patient in loratadine clinical trials.

blepharospasm, blurred vision, conjunctivitis, ocular pain

Conjunctivitis (2%) was reported in children 6 to 12 years of age during clinical trials for loratadine. Altered lacrimation, blurred vision, ocular pain, and blepharospasm have been reported in at least one adult or pediatric patient receiving loratadine during clinical trials.

elevated hepatic enzymes, hepatic necrosis, hepatitis, jaundice

Hepatic adverse reactions to loratadine are rare. Abnormal hepatic function including elevated hepatic enzymes, jaundice, hepatitis, and hepatic necrosis have been reported during postmarketing experience with loratadine.

thrombocytopenia

Thrombocytopenia has been reported rarely during postmarketing experience with loratadine.

Description

Loratadine is a non-sedating, selective peripheral antihistamine (H1-receptor antagonist) that is similar in structure to azatadine. Due to poor penetration into the central nervous system (CNS), a low affinity for central histamine H1-receptors, and a greater affinity for peripheral H1-receptors, the drug is less likely to cause sedation or other CNS effects compared with traditional, sedating antihistamines. Unlike older, off-market second generation antihistamines like astemizole, loratadine does not cause QT prolongation with usual clinical dosages. Loratadine is primarily used in adult and pediatric populations as young as 2 years of age for seasonal allergic rhinitis and chronic spontaneous urticaria. Loratadine was FDA-approved in 1993; the FDA granted nonprescription (OTC) status in 2003.

Mechanism Of Action

Loratadine is highly selective for histamine H1-receptors. Unlike cromolyn and nedocromil which block histamine release, H1-antagonists compete with free histamine for binding at H1-receptor sites. This competitive antagonism blocks the effects of

histamine on H1-receptors in the gastrointestinal tract, uterus, large blood vessels, and bronchial muscle. Loratadine does not readily cross the blood-brain barrier, and it preferentially binds at H1-receptors in the periphery rather than within the brain, which probably accounts for some of its non-sedating character. H1-blockers are similar in structure to anticholinergics, local anesthetics, antispasmodics, and ganglionic- and adrenergic-blocking agents, sharing some of their properties. Loratadine does not exert significant anticholinergic effects at therapeutic concentrations. In vitro studies have shown that loratadine has a weak affinity for acetylcholine and alpha-adrenergic receptors.

Pharmacokinetics

Loratadine is administered orally. It is 97% protein-bound. Loratadine has a high first-pass effect and is almost completely metabolized in the liver to the an active metabolite, descarboethoxyloratadine (DCL, also known as desloratadine). In vitro studies indicate that metabolism to DCL occurs predominantly by CYP3A4 and, to a lesser extent, by cytochrome CYP2D6. In the presence of a CYP3A4 inhibitor, loratadine is metabolized to DCL predominantly by CYP2D6. Approximately 80% of the total loratadine dose administered can be found equally distributed between urine and feces in the form of metabolic products within 10 days. The mean elimination half-lives in normal adult subjects (n = 54) were 8.4 hours (range: 3 to 20 hours) for loratadine and 28 hours (range: 8.8 to 92 hours) for desloratadine. There was considerable variability in the pharmacokinetic data in all studies of the oral dosage forms, probably due to the extensive first-pass metabolism.

Affected cytochrome P450 isoenzymes and drug transporters: CYP3A4, CYP2D6, P-gp
Metabolism of loratadine occurs predominantly by CYP3A4 and, to a lesser extent, by cytochrome CYP2D6. Concurrent administration with either ketoconazole, erythromycin (both CYP3A4 inhibitors), or cimetidine (CYP2D6 and CYP3A4 inhibitor) to healthy volunteers was associated with increased plasma concentrations of loratadine. However, in drug-drug interaction studies there were no clinically relevant changes in the safety profile of loratadine associated with these increases. Loratadine is also a substrate for P-gp transport; however, no clinically significant drug-drug interactions have been reported with P-gp inhibitors.

Route-Specific Pharmacokinetics

- **Oral Route**

After oral administration, the onset of action of loratadine occurs within 1 to 3 hours, with peak effects in 8 to 12 hours and a duration of action greater than 24 hours. Administration with food increases absorption and AUC up to 40% for the syrup or

tablets and up to 48% for the rapidly-disintegrating tablets. The time to peak concentrations (Tmax) is delayed by administration with food. However, since the clinical response is unaffected, the drug can be administered without regard to meals. Loratadine and desloratadine reach steady-state in most patients by approximately the fifth dosing day.

- **Hepatic Impairment**

In 7 subjects with chronic alcoholic liver disease, the AUC and Cmax of loratadine were doubled while the pharmacokinetic profile of desloratadine was not substantially different from that observed in other trials enrolling normal subjects. The elimination half-lives for loratadine and desloratadine were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease.

- **Renal Impairment**

Peak serum concentrations of loratadine increase up to 73%, and desloratadine up to 120%, in the presence of severe renal impairment (CrCL less than 30 mL/minute) as compared to subjects with normal renal function. The mean elimination half-lives of loratadine (7.6 hours) and desloratadine (23.9 hours) were not substantially different from normal subjects. Hemodialysis does not have an effect on the pharmacokinetics of loratadine or desloratadine in subjects with chronic renal impairment
.30768

- **Pediatrics**

Children 6 to 12 years
The pharmacokinetic profile of loratadine in children ages 6 to 12 years is similar to that of adults. The pharmacokinetic parameters (AUC and Cmax) of 13 children (aged 8 to 12 years) receiving a single-dose of 10 mg loratadine syrup were comparable to those following administration of a 10 mg tablet or syrup to adult volunteers.

Children 2 to 5 years
The pharmacokinetic profile of loratadine in children (2 to 5 years of age) is similar to that of adults. The pharmacokinetic parameters (AUC and Cmax) of 18 children (aged 2 to 5 years) receiving a single-dose of 5 mg loratadine syrup were comparable to those after administration of a 10 mg tablet or syrup to adult volunteers or children 8 years of age and older.

- **Geriatric**

In geriatric subjects (66 to 78 years of age), the AUC and peak plasma concentrations of loratadine are roughly 50% greater than those observed in young adults. The mean elimination half-lives for the geriatric subjects were 18.2 hours (range: 6.7 to 37 hours) for loratadine and 17.5 hours (range: 11 to 38 hours) for desloratadine.

Administration

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

Oral Administration

Loratadine may be administered without regard to meals.

Oral Solid Formulations

Chewable tablets (e.g., Claritin Chewable)
Crush or have patient chew thoroughly before swallowing.

Tablets or Liquid-filled capsules (e.g., Claritin or Claritin Liqui-gels)
Have patient swallow tablet or capsule with water or other liquid.

Oral rapidly-disintegrating tablets (ODT) (e.g., Claritin Reditabs)
Open blister package with dry hands; use tablet immediately after removing from package. Do not use ODT if an individual blister package has been opened or torn.
Place tablet on patient's tongue; dissolution occurs rapidly. Have patient swallow after dissolved.
May administer with or without water.

Oral Liquid Formulations

Oral syrup or solution
Measure dosage using a calibrated measuring device, such as an oral syringe, to ensure accurate dosing.

Maximum Dosage Limits

- **Adults**
  10 mg/day PO.
- **Geriatric**
  10 mg/day PO.
- **Adolescents**
  10 mg/day PO.
- **Children**
  6 to 12 years: 10 mg/day PO.
  2 to 5 years: 5 mg/day PO.

1 year: Safety and efficacy have not been established.

- **Infants**
  Safety and efficacy have not been established.
- **Neonates**
  Safety and efficacy have not been established.

Dosage Forms

- Alavert 24 Hour Allergy 10mg Orally Disintegrating Tablet (Fresh Mint)
- Alavert 24 Hour Allergy Orally Disintegrating Tablet (Citrus Burst)
- Alavert 24 Hour Allergy Orally Disintegrating Tablet (Citrus Burst)
- Alavert 24 Hour Allergy Orally Disintegrating Tablet (Fresh Mint)
- Alavert D-12 Hour Allergy & Congestion Extended Release Tablet
- Alavert D-12 Hour Allergy & Sinus ExtendedRelease Tablet
- Allergy & Congestion Relief 12 Hour 5mg-120mg Extended-Release Tablet
- Allergy Relief & Nasal Decongestant 24 Hour Non-Drowsy 10mg-240mg Extended-Release Tablet
- Allergy Relief 10mg Tablet
- Allergy Relief 10mg Tablet
- Allergy Relief-D 24 Hour 10mg-240mg Extended-Release Tablet
- Allergy-D 12 Hour Non-Drowsy 120mg-5mg Extended-Release Tablet
- Allergy-D 24 Hour Non-Drowsy 10mg-240mg Extended-Release Tablet
- CAREALL Allergy Relief 24 Hour 10mg Tablet
- Claritin 10mg Chewable Tablet (Cool Mint)
- Claritin 10mg Liqui-Gel Capsule
- Claritin 10mg Liqui-Gel Capsule
- Claritin 10mg Tablet
- Claritin 24 Hour Allergy 10mg Chewable Tablet (Cool Mint)
- Claritin 24 Hour Allergy 10mg Tablet
- Claritin 24 Hour Allergy 10mg Tablet
- Claritin Children's 5mg Chewable Tablet
- Claritin Children's 5mg Chewable Tablet (BubbleGum)
- Claritin Children's 5mg Chewable Tablet (Grape)
- Claritin Children's 5mg/5mL Solution (Grape)
- Claritin Children's 5mg/5ml Syrup (Fruit)
- Claritin Children's Allergy 5mg/5mL 24 hour Relief Solution (Grape)
- Claritin Children's Allergy 5mg/5mL Solution (Grape)
- Claritin Children's Non-Drowsy Allergy Sugar Free 5mg/5mL Solution (Grape)
- Claritin Children's RediTabs 24 Hour 10mg Orally Disintegrating Tablet
- Claritin Children's RediTabs 24 Hour 10mg Orally Disintegrating Tablet

- Claritin RediTabs 10mg Orally Disintegrating Tablet
- Claritin RediTabs 12 Hour 5mg Orally Disintegrating Tablet
- Claritin RediTabs 24 Hour 10mg Orally Disintegrating Tablet
- Claritin RediTabs 24 Hour 10mg Orally Disintegrating Tablet
- Claritin-D 12 Hour 5mg-120mg Extended-Release Tablet
- Claritin-D 24 Hour 10mg-240mg Extended-Release Tablet
- Claritin-D 24 Hour 10mg-240mg Extended-Release Tablet
- CVS Allergy Relief Non-Drowsy 10mg Orally Disintegrating Tablet
- CVS Allergy Relief Non-Drowsy 10mg Tablet
- CVS Allergy Relief Non-Drowsy 12 Hour 5mg Orally Disintegrating Tablet
- CVS Allergy Relief-D 12 Hour Extended-Release Tablet
- CVS Allergy Relief-D 24 Hour 10mg-240mg Extended-Release Tablet
- CVS Children's Allergy Relief 5mg Chewable Tablet (Bubble Gum)
- CVS Children's Allergy Relief 5mg Chewable Tablet (Grape)
- CVS Children's Allergy Relief 5mg/5ml Solution (Grape)
- CVS Children's Loratadine 5mg Chewable Tablet (Grape)
- Equaline Allergy Relief Non-Drowsy 10mg Tablet
- Equate Allergy & Congestion Relief 12 Hour 5mg-120mg Extended-Release Tablet
- Equate Allergy Relief 24 Hour 10mg Tablet
- Equate Allergy Relief and Nasal Decongestant 10mg-240mg 24 Hour Extended-Release Tablet
- Equate Children's Allergy 5mg/5mL Sugar-Free Solution (Grape)
- Equate Children's Allergy Relief 5mg/5mL Solution (Grape)
- Equate Children's Allergy Relief 5mg/5mL Sugar Free Solution (Grape)
- Equate Children's Loratadine 10mg Orally Disintegrating Tablet (Peppermint)
- Equate Children's Non-Drowsy Loratadine 5mg Chewable Tablet (Grape)
- Equate Loratadine 24 Hour 10mg Orally Disintegrating Tablet
- Equate Non-Drowsy All Day Allergy Relief 24 Hour 10mg Tablet
- Foster & Thrive All Day Allergy Relief 24 Hour Relief 10mg Tablet
- Foster & Thrive Allergy D-12 Hour 120mg-5mg Extended-Release Tablet
- Foster & Thrive Allergy Relief 10mg Tablet
- Foster & Thrive Allergy Relief Non-Drowsy 10mg Tablet
- Foster & Thrive Children's Allergy Relief 5mg Chewable Tablet (Grape)
- GNP Allergy & Congestion Relief 24 Hour Extended-Release Tablet
- GNP Allergy & Congestion Relief Non-Drowsy 10mg-240mg 24 Hour Extended-Release Tablet
- GNP Children's Loratadine 5mg/5mL Sugar-Free Solution (Grape)
- GNP Children's Loratadine Non-Drowsy 5mg/5mL Solution (Fruit)
- GNP Children's Non-Drowsy Loratadine 5mg/5mL Solution (Grape)
- GNP ClearTime Indoor & Outdoor Allergies 24 Hour 10mg Tablet

- GNP Loratadine 10mg Tablet
- GNP Loratadine 24 Hour 10mg Orally Disintegrating Tablet
- GNP Loratadine D 12 Hour 5mg-120mg Extended-Release Tablet
- GNP Loratadine-D 12 Hour 5mg-120mg Extended-Release Tablet
- GNP Non-Drowsy Allergy Relief Orally Disintegrating Tablet
- GNP Non-Drowsy Loratadine 24 Hour 10mg Tablet
- GoodSense 24 Hour Allergy Relief Non-Drowsy 10mg Softgel
- Goodsense Children's Allergy Relief Dye-Free 5mg/5mL Solution (Grape)
- GoodSense Non-Drowsy Allergy Relief 24 Hour 10mg Tablet
- HEB Allergy Relief-D 24 Hour 10mg-240mg Extended-Release Tablet
- Kirkland AllerClear D-12 Hour 5mg-120mg Extended-Release Tablet
- Kirkland AllerClear D-24 Hour 10mg-240mg Extended-Release Tablet
- Kirkland AllerClear-D 24 Hour 10mg-240mg Extended-Release Tablet
- Kirkland Non-Drowsy ALLERCLEAR 10mg Tablet
- Leader Allergy Relief 10mg Tablet
- Leader Allergy Relief 5mg/5ml Solution (Fruit)
- Leader Allergy Relief D-12 5mg-120mg Extended-Release Tablet
- Leader Allergy Relief D-24 Non-Drowsy Extended-Release Tablet
- Leader Allergy Relief Non-Drowsy 10mg Orally Disintegrating Tablet
- Leader Children's Allergy Relief 5mg/5ml Solution (Grape)
- Leader Loratadine 10mg Tablet
- Leader Non-Drowsy Allergy Relief 10mg Tablet
- Loratadine 10mg Oral capsule, liquid filled
- Loratadine 10mg Oral disintegrating tablet
- Loratadine 10mg Oral tablet
- Loratadine 10mg Tablet
- Loratadine 5mg Chewable tablet
- Loratadine 5mg, Pseudoephedrine Sulfate 120mg Oral tablet, extended release 12 hour
- Loratadine 5mg/5mL Oral solution
- Loratadine Bulk powder
- Medique Loradamed 24 Hour Allergy Relief 10mg Tablet
- Meijer Allergy Relief-D 24 Hour 10mg-240mg Extended-Release Tablet
- Picnic Allergy Relief 24 Hour 10mg Tablet
- Premier Value Allergy Relief and Nasal Congestant 24 Hour Extended-Release Tablet
- Premier Value Allergy Relief and Nasal Decongestant 10mg-240mg 24 Hour Extended-Release Tablet
- Premier Value Allergy Relief Non-Drowsy 10mg Tablet
- Premier Value Children's Loratadine Non-Drowsy 5mg/5mL Solution (Grape)

- Pseudoephedrine Sulfate 240mg, Loratadine 10mg Oral tablet, extended release 24 hour
- Publix Allergy Relief 10mg Tablet
- Publix Allergy Relief 24 Hour Orally Disintegrating Tablet
- Publix Allergy Relief D 12 Hour Extended-Release Tablet
- Publix Allergy Relief D 24 Hour Extended-Release Tablet
- Quality Choice Allergy Relief 10mg Tablet
- Quality Choice Allergy Relief and Nasal Decongestant 24 Hour 10mg-240mg Extended-Release Tablet
- Quality Choice Allergy Relief Non-Drowsy 10mg Orally Disintegrating Tablet
- Quality Choice Allergy Relief Non-Drowsy 10mg Softgel
- Quality Choice Allergy Relief Non-Drowsy 10mg Tablet
- RITE AID Allergy & Congestion Relief 12 Hour Extended-Release Tablet
- RITE AID Allergy Relief 24 Hour 10mg Tablet
- RITE AID Children's Non-Drowsy Allergy Relief 5mg/5mL Solution (Fruit)
- RITE AID Children's Non-Drowsy Allergy Relief 5mg/5ml Solution (Grape)
- Select Brand Loratadine 10mg Tablet
- Sunmark Loratadine 24 Hour 10mg Non-Drowsy Tablet
- Tavist ND 10mg Tablet
- Today's Health Loratadine Allergy 24 Hour 10mg Orally Disintegrating Tablet
- Today's Health Loratadine Allergy Relief 10mg Tablet
- Today's Health Loratadine-D 24 Hour 10mg-240mg Extended-Release Tablet
- Top Care Allergy Relief Non-Drowsy 10mg Tablet
- TopCare 12 Hour Allergy & Congestion Relief 5mg-120mg Extended-Release Tablet
- TopCare Children's Allergy 5mg/5mL Solution (Grape)
- TopCare Children's Loratadine 5mg/5mL Syrup (Grape)
- Wal-itin 24 Hour Allergy 10mg Tablet
- Wal-itin Aller-Melts 10mg Orally Disintegrating Tablet
- Wal-itin Allergy Relief Non-Drowsy 10mg Orally Disintegrating Tablet
- Wal-itin Allergy Relief Tablet
- Wal-itin Children's 5mg/5mL Solution
- Wal-itin Children's Allergy 10mg Orally Disintegrating Tablet
- Wal-Itin Children's Allergy 5mg Chewable Tablet (Bubble Gum)
- Wal-Itin Children's Allergy 5mg Chewable Tablet (Grape)
- Wal-itin Children's Allergy 5mg/5mL Solution (Bubblegum)
- Wal-itin Children's Allergy 5mg/5ml Solution (Grape)
- Wal-itin D 12 Hour Allergy & Congestion Extended-Release Tablet
- Wal-itin D 12 Hour Extended-Release Tablet
- Wal-itin D 24 Hour Allergy & Congestion Extended-Release Tablet
- Wal-vert 10mg Orally Disintegrating Tablet

- Walgreens Allergy Relief 24 Hour 10mg Tablet
- Walgreens Allergy Relief 24 Hour Relief 10mg Tablet
- Walgreens Allergy Relief D12 5mg-120mg Extended-Release Tablet
- Walgreens Allergy Relief Non-Drowsy 10mg Softgel
- Walgreens Allergy Relief Non-Drowsy 12 Hour 5mg Orally Disintegrating Tablet
- Walgreens Allergy Relief Non-Drowsy 24 Hour 10mg Orally Disintegrating Tablet
- Walgreens Children's Allergy Relief 5mg/5mL Solution (Grape)
- Walgreens Junior's Allergy Relief Non-Drowsy 10mg Orally Disintegrating Tablet
- Walgreens Loratadine 10mg Tablet
- Walgreens Non-Drowsy Allergy Relief D 24 Hour Allergy & Congestion 10mg-240mg Extended-Release Tablet
- Walgreens Non-Drowsy Allergy Relief D 24 Hour Nasal Decongestant 10mg-240mg Extended-Release Tablet
- Walgreens Non-Drowsy Allergy Relief D12 12 Hour 120mg-5mg Extended-Release Tablet

Dosage Adjustment Guidelines

Hepatic Impairment

Adjust dosage as follows for hepatic impairment:
Adults: Reduce initial dosage to 10 mg PO every other day.
6 to 17 years of age: Reduce initial dosage to 10 mg PO every other day.
2 to 5 years of age: Reduce initial dose to 5 mg PO every other day.

Renal Impairment

CrCl 30 mL/minute or greater: No adjustment needed.
CrCl less than 30 mL/minute: Adjust dosage as follows:
Adults: Reduce initial dose to 10 mg PO every other day.
6 to 17 years of age: Reduce initial dose to 10 mg PO every other day.
2 to 5 years of age: Reduce initial dose to 5 mg PO every other day.

Intermittent hemodialysis
See dosage for patients with CrCl less than 30 mL/minute. Loratadine and its active metabolite are not removed by hemodialysis.