Brand Names

Clarinex, Clarinex RediTab

Indication Specific Dosing

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

Oral dosage (tablet)

Adults

5 mg PO once daily.

Children and Adolescents 12 years and older

5 mg PO once daily.

Oral dosage (orally disintegrating tablet)

Adults

5 mg PO once daily.

Children and Adolescents 12 years and older

5 mg PO once daily.

Children 6 to 11 years

2.5 mg PO once daily.

Oral dosage (oral solution)

Adults

5 mg PO once daily.

Children and Adolescents 12 years and older

5 mg PO once daily.

Children 6 to 11 years

2.5 mg PO once daily.

Children 1 to 5 years

1.25 mg PO once daily. NOTE: Desloratadine is not FDA-approved for the treatment of seasonal allergic rhinitis in children less than 2 years.

Infants 6 months and older

1 mg PO once daily. NOTE: Desloratadine is not FDA-approved for the treatment of seasonal allergic rhinitis in infants.

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

Oral dosage (tablet)

Adults

5 mg PO once daily.

Children and Adolescents 12 years and older

5 mg PO once daily.

Oral dosage (orally disintegrating tablet)

Adults

5 mg PO once daily.

Children and Adolescents 12 years and older

5 mg PO once daily.

Children 6 to 11 years

2.5 mg PO once daily.

Oral dosage (oral solution)

Adults

5 mg PO once daily.

Children 6 to 11 years

2.5 mg PO once daily.

Children and Adolescents 12 years and older

5 mg PO once daily.

Children 1 to 5 years

1.25 mg PO once daily.

Infants 6 months and older

1 mg PO once daily.

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. Desloratadine is a metabolite of loratadine and should not be used in patients with loratadine hypersensitivity.

renal failure, renal impairment

People with renal impairment or renal failure should ask their care team before using desloratadine. A reduced initial dosage of desloratadine is recommended for adults and adolescents with renal impairment. Dosing recommendations for children less than 12 years of age with renal impairment cannot be made due to lack of data.

hepatic failure

People with hepatic impairment, including hepatic failure, should ask their care team before using desloratadine since it is extensively metabolized in the liver. A reduced initial dosage of desloratadine is recommended for adults and adolescents with hepatic impairment. Dosing recommendations for children less than 12 years of age with hepatic impairment cannot be made due to lack of data.

children, infants, neonates

Desloratadine is approved for prescription use in children and infants as young as 6 months of age. Due to the risk for serious adverse reactions, the FDA recommends against administration of over the counter (OTC) cough and cold 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.

phenylketonuria

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

pregnancy

Desloratadine is the major metabolite of loratadine. Results of a large cohort study of desloratadine use in human pregnancy concluded that the safety profile of desloratadine is similar to loratadine and cetirizine. No teratogenic or mutagenic effects of desloratadine were observed in animal reproductive studies in rats or rabbits. Loratadine and cetirizine are often preferred second generation antihistamines based on their excellent safety data and recommendation in multiple guidelines for use during pregnancy.

breast-feeding

Desloratadine may be used during breast-feeding. It is distributed into breast milk in low amounts. The safety profile of desloratadine during lactation is expected to be similar to loratadine, the parent drug. Data from loratadine use during lactation suggests that because of its expected low milk levels and lack of sedation and anticholinergic effects,

maternal use of desloratadine is also unlikely to adversely affect a breastfed infant or milk production. Guidelines recommend loratadine or cetirizine at the lowest dose as preferred antihistamines in breast-feeding individuals.

Pregnancy And Lactation

Desloratadine is the major metabolite of loratadine. Results of a large cohort study of desloratadine use in human pregnancy concluded that the safety profile of desloratadine is similar to loratadine and cetirizine. No teratogenic or mutagenic effects of desloratadine were observed in animal reproductive studies in rats or rabbits. Loratadine and cetirizine are often preferred second generation antihistamines based on their excellent safety data and recommendation in multiple guidelines for use during pregnancy.

Interactions

Acetaminophen; Aspirin; diphenhydrAMINE: (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.
Acetaminophen; Caffeine; Pyrilamine: (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.
Acetaminophen; Chlorpheniramine: (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.
Acetaminophen; Chlorpheniramine; Dextromethorphan: (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.
Acetaminophen; Chlorpheniramine; Dextromethorphan; Phenylephrine: (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.
Acetaminophen; Chlorpheniramine; Dextromethorphan; 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.
Acetaminophen; Chlorpheniramine; Phenylephrine : (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.
Acetaminophen; Dextromethorphan; Doxylamine: (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.
Acetaminophen; diphenhydrAMINE: (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.
Acetaminophen; Pamabrom; Pyrilamine: (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.
Brompheniramine: (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.
Brompheniramine; Dextromethorphan; Phenylephrine: (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.
Brompheniramine; Phenylephrine: (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.
Brompheniramine; 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.
Brompheniramine; Pseudoephedrine; Dextromethorphan: (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.
Carbinoxamine: (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.
Cetirizine: (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.
Cetirizine; 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.
Chlophedianol; Dexbrompheniramine: (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.
Chlophedianol; Dexchlorpheniramine; 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.
Chlorcyclizine: (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.
Chlorpheniramine: (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.
Chlorpheniramine; Codeine: (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.
Chlorpheniramine; Dextromethorphan: (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.
Chlorpheniramine; Dextromethorphan; Phenylephrine: (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.
Chlorpheniramine; Dextromethorphan; 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.
Chlorpheniramine; HYDROcodone: (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.
Chlorpheniramine; Ibuprofen; 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.
Chlorpheniramine; Phenylephrine: (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.
Chlorpheniramine; 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.
Clemastine: (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.
Codeine; Dexbrompheniramine: (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.
Cyproheptadine: (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.
Dexbrompheniramine: (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.
Dexbrompheniramine; Dextromethorphan; Phenylephrine: (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.
Dexbrompheniramine; 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.
Dexchlorpheniramine: (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.
Dexchlorpheniramine; Dextromethorphan; 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.
Dextromethorphan; diphenhydrAMINE; Phenylephrine: (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.
dimenhyDRINATE: (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.
diphenhydrAMINE: (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.
diphenhydrAMINE; Ibuprofen: (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.
diphenhydrAMINE; Naproxen: (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.
diphenhydrAMINE; Phenylephrine: (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.
Doxylamine: (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.
Doxylamine; Pyridoxine: (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.
Fexofenadine: (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.
Fexofenadine; 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.
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 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.
Levocetirizine: (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.
Loratadine: (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.
Loratadine; 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.
Meclizine: (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.
Pseudoephedrine; Triprolidine: (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.
Sedating H1-blockers: (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.
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 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.

Adverse Reaction

dizziness, drowsiness, dysmenorrhea, fatigue, headache, myalgia, pharyngitis, xerostomia

Poor penetration into the central nervous system (CNS) and a low affinity for CNS H1-receptors help limit CNS effects of desloratadine, a non-sedating H1 blocker. While fatigue (2.1% to 5%) and somnolence (2.1% adults; 9.1% pediatrics) do occur in some patients, the risk of drowsiness is relatively low as compared to standard, sedating antihistamines. During pre-marketing clinical trials, other adverse reactions reported in 2% or more of adult and pediatric patients receiving desloratadine and that were more frequently experienced as compared to placebo-treated patients include headache (14%), pharyngitis (3% to 4.1% adults; 3.1% to 4.5% pediatrics), xerostomia (3%), dizziness (4%), dry throat (2%), flu-like symptoms (2%), myalgia (2.1% to 3%), and dysmenorrhea (2.1%).

anaphylactoid reactions, dyspnea, edema, elevated hepatic enzymes, hepatitis, hyperbilirubinemia, palpitations, pruritus, rash, sinus tachycardia, urticaria

The following spontaneous adverse events have been reported during marketing of desloratadine: tachycardia (sinus tachycardia), palpitations and rarely hypersensitivity reactions (such as rash (unspecified), pruritus, urticaria, edema, dyspnea, and anaphylactoid reactions), elevated hepatic enzymes including bilirubin (hyperbilirubinemia), and rare cases of hepatitis.

cough, epistaxis, fever, infection, rhinorrhea

Respiratory and infectious adverse reactions reported in pediatric patients aged 6 months to 5 years receiving desloratadine and that were more frequently experienced

as compared to placebo-treated patients include fever (5.5% to 16.9%), upper respiratory tract infection (10.8% to 21.2%), cough (10.6% to 10.8%), bronchitis (6.1%), otitis media (6.1%), rhinorrhea (4.5%), urinary tract infection (3.6%), varicella (3.6%), epistaxis (3.1%), and parasitic infection (3.1%).

anorexia, appetite stimulation, diarrhea, dyspepsia, nausea, vomiting

Nausea (5% adults; 3% pediatrics) is the most common gastrointestinal adverse reaction reported in desloratadine clinical trials. Dyspepsia was reported by 3% of adult subjects. In pediatric patients aged 6 months to 5 years, the following GI adverse events were more experienced more frequently in patients who received desloratadine than those who received placebo: diarrhea (15.4% to 19.7%), vomiting (6.1%), anorexia (4.5%), and appetite stimulation (3.1%).

dystonic reaction, emotional lability, hyperactivity, insomnia, involuntary movements, irritability, restlessness, seizures

Central nervous system adverse reactions reported in pediatric patients aged 6 months to 5 years receiving desloratadine and that were more frequently experienced as compared to placebo-treated patients include irritability (12.1%), insomnia (4.5%), and emotional lability (3.1%). Seizures, psychomotor hyperactivity (restlessness), and involuntary movements including dystonic reaction, tics, and extrapyramidal symptoms have been reported during postmarketing use of desloratadine.

erythema, maculopapular rash

Dermatologic adverse reactions reported in pediatric patients aged 6 months to 5 years receiving desloratadine and that were more frequently experienced as compared to placebo-treated patients include maculopapular rash (3.1%) and erythema (3%).

Description

Desloratadine is a non-sedating, potent, second-generation long-acting antihistamine (H1-blocker). Desloratadine is the active metabolite of loratadine, with a relative potency of 10 to 20 times that of loratadine in vitro. Both loratadine and desloratadine are non-sedating; however, desloratadine does not cause QT prolongation, even when given in doses 4 to 9 times the recommended dose in adults. Desloratadine is utilized in adults and adolescents to relieve symptoms associated with seasonal allergic rhinitis, perennial allergic rhinitis, and chronic spontaneous urticaria. Desloratadine was originally FDA approved in December 2001.

Mechanism Of Action

Desloratadine 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 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. In vitro studies have demonstrated that desloratadine has a 15-fold higher affinity for the H1-receptor than does the parent compound, loratadine.

Desloratadine 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 nonsedating character. H1-blockers are similar in structure to anticholinergics, local anesthetics, antispasmodics, and ganglionic- and adrenergic-blocking agents, sharing some of their properties. H1-blockers possess anticholinergic properties in varying degrees; however, desloratadine does not exert significant anticholinergic effects at therapeutic concentrations.

In patients with allergic rhinitis, the inflammatory response plays a prominent role in the development of nasal obstruction and involves a number of mediators. Initial release of histamine from mast cells is followed by late-phase reactions involving a number of other cells, such as fibroblasts, epithelial cells, neutrophils, eosinophils (especially in conditions with raised IgE levels), macrophages, platelets, and lymphocytes. Cell adhesion can also be part of the inflammatory process. Desloratadine has demonstrated anti-inflammatory effects in both in vitro and in vivo studies. The anti-inflammatory action appears to be related to a reduction in eosinophils, neutrophils, interleukin-4 and interleukin-8.

Pharmacokinetics

Desloratadine is administered orally. It is extensively metabolized and only minimal amounts of the orally administered dose are recovered in the urine (less than 2%) and feces (less than 7%). The major metabolic pathway is hydroxylation to form 3-OH-desloratadine that is glucoronidated and the glucuronide conjugate is excreted in the urine and bile. The elimination plasma half-life is approximately 20 to 30 hours. Steady state plasma concentrations are attained in 4 to 6 days.

Affected cytochrome P450 (CYP450) isoenzymes and drug transporters: None
Clinically relevant drug interactions related to inhibition of CYP450 system enzymes, such as CYP3A4, or drug transporters (such as P-glycoprotein) with desloratadine have not been noted in drug-drug interaction studies. Desloratadine is a CYP3A4 and P-gp substrate. Increased plasma concentrations (Cmax and AUC) of desloratadine and 3-hydroxydesloratadine were observed with some potent CYP3A4 inhibitors in studies. However, there were no clinically relevant changes in the safety profile of desloratadine, as assessed by electrocardiographic parameters (including the corrected QT interval), clinical laboratory tests, vital signs and adverse events.

Route-Specific Pharmacokinetics

- **Oral Route**

Peak plasma concentrations are obtained 3 hours after a 5 mg oral dose of the conventional tablets. Food has no effect on the extent of desloratadine absorption. The conventional tablet, disintegrating tablet, and oral solution are bioequivalent.

- **Hepatic Impairment**

Patients with hepatic impairment, regardless of severity, have demonstrated mean desloratadine AUC values 2.4 times greater than the normal patient population. An increase in the mean elimination half-life of desloratadine is observed in these patients. Dosage adjustments for patients with hepatic impairment are recommended.

- **Renal Impairment**

In adult patients with mild (CrCl 51 to 69 mL/minute/1.73 m2) or moderate (CrCl 34 to 43 mL/minute/1.73 m2) renal impairment, the median Cmax and AUC values increased 1.2- and 1.9-fold, respectively relative to subjects with normal renal function. In adult patients with severe renal impairment or who were hemodialysis dependent, median Cmax and AUC values increase by approximately 1.7- and 2.5-fold, respectively. Minimal changes in 3-OH-desloratadine were observed. Dosage adjustments of desloratadine are recommended for patients with renal impairment.

- **Pediatrics**

Children 2 to 11 years
In a pharmacokinetic study, children (6 to 11 years of age) receiving a single dose of desloratadine 2.5 mg PO had plasma concentrations similar to those achieved in adults receiving 5 mg PO. In children (2 to 5 years of age), a single dose of desloratadine 1.25 mg resulted in desloratadine plasma concentrations similar to those achieved in adults receiving 5 mg PO. However, the Cmax and AUC of the metabolite (3-hydroxydesloratadine) were 1.27 and 1.61 times higher for adults compared to the Cmax and AUC obtained in children 2 to 11 years of age.

Infants and Children less than 2 years

In a pharmacokinetic study, children (6 to 23 months of age) were given a single dose of either 1.25 mg or 0.625 mg desloratadine PO. The results indicated that a dose of 1 mg for subjects aged 6—11 months and 1.25 mg for subjects 12—23 months of age is required to obtain desloratadine plasma concentrations similar to those achieved in adults administered a single 5 mg oral dose.

- **Geriatric**

Elderly patients over 65 years old have shown mean AUC and Cmax values which were 20% greater than those of younger adults. The mean plasma elimination half-life was prolonged by approximately 30%. Dosage adjustment of desloratadine does not appear to be warranted in the elderly population.

- **Gender Differences**

AUC and Cmax values are not significantly different among gender, so no dosage adjustment among this group is necessary with desloratadine use.

- **Ethnic Differences**

AUC and Cmax values are not significantly different among race, so no dosage adjustment among this group is necessary with desloratadine use.

- **Other**

Slow metabolizers
Slow metabolizers of desloratadine have been identified. In this patient population (which is estimated at 4%), half-lives are much longer (up to 60 hours), and median AUC values are approximately 6-fold higher. However, major differences in safety have not been observed between slow and normal metabolizers; however, an increased risk of exposure-related adverse events in patients who are poor metabolizers cannot be ruled out. The major elimination pathway for slow metabolizers is via excretion of unchanged drug in the urine and feces.

Administration

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

Oral Administration

Oral Solid Formulations

Tablets: Swallow tablets whole, do not chew.
Disintegrating Tablets: Administer by placing on the tongue. The tablet will dissolve rapidly until it can be swallowed in the saliva. Food or water do not affect bioavailability.

Oral Liquid Formulations

Oral syrup (0.5 mg/mL): Measure dose using a calibrated oral syringe, cup, or dropper.

Maximum Dosage Limits

- **Adults**
  5 mg/day PO.
- **Geriatric**
  5 mg/day PO.
- **Adolescents**
  5 mg/day PO.
- **Children**
  12 years: 5 mg/day PO.
  6 to 11 years: 2.5 mg/day PO.
  1 to 5 years: 1.25 mg/day PO.
- **Infants**
  6 to 11 months: 1 mg/day PO.
  Less than 6 months: Safety and efficacy have not been established.

Dosage Forms

- Clarinex 5mg Tablet
- Clarinex 5mg Tablet
- Clarinex-D 12 Hour 2.5mg-120mg Extended-Release Tablet
- Desloratadine 0.5mg/1mL Oral solution
- Desloratadine 2.5mg Oral disintegrating tablet
- Desloratadine 5mg Oral disintegrating tablet
- Desloratadine 5mg Oral tablet

Dosage Adjustment Guidelines

Hepatic Impairment

In adults with hepatic impairment, a starting dose of 5 mg PO every other day is recommended. Recommendations for dosage adjustments in pediatric patients with hepatic impairment are not available, but dosage interval adjustment may be necessary.

Renal Impairment

CrCl 50 mL/minute or less: In adults, 5 mg PO every other day is recommended. Recommendations for dosage adjustments in pediatric patients with renal impairment are not available, but dosage interval adjustment may be necessary.

Intermittent hemodialysis
Desloratadine and its metabolite are not removed by hemodialysis. See dosage for CrCl 50 mL/minute or less.