CLARISTINE

Tablet & Syrup

Composition

Claristine Tablets
Each tablet contains 10 mg Loratadine.

Claristine Syrup
Each 5 ml of the syrup contains 5 mg Loratadine.

Action

Loratidine is a potent long-acting non-sedating antihistamine, with selective peripheral H1-receptors antagonistic activity. Loratadine does not readily penetrate into the central nervous system. Loratadine exhibits greater affinity for peripheral H1-receptors than for central H1-receptors. These properties account for the observed lack of sedation. Loratadine does not exhibit anticholinergic activity in animals.

Pharmacokinetics
Loratadine is well absorbed with peak plasma levels occurring at approximately one hour after dosing. The drug is almost much metabolised. It has an active metabolite, descarboethoxyloratadine; this metabolite corresponds to 1% to 2% of the dose. Loratadine is extensively bound to plasma protein (97 to 99%) and, descarboethoxyloratadine moderately bound (73 to 76%).

Approximately 40% of the dose is excreted in the urine and 42% in the faeces in a 10-day period. Approximately 27% of the dose is eliminated in the urine during the first 24 hours. The half-life of loratadine is 15 hours while that of descarboethoxyloratadine is 12 hours. The terminal elimination phase half-life, based on plasma radioactivity, is approximately 46 hours.

Indications

Claristine is indicated for the relief of nasal and non-nasal symptoms of seasonal allergic rhinitis and for the treatment of chronic idiopathic urticaria in patients 6 years of age or older.

Contraindications

Loratadine is contraindicated in patients who are hypersensitive to this medication or to any of its ingredients.

Precautions

General
Patients with liver impairment or renal insufficiency (GFR < 30 mL/min) should be given a lower initial dose (10 mg every other day).

Pregnancy
Category B
Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

Nursing Mothers
Caution should be exercised when Loratadine is administered to a nursing woman.

Pediatric Use
The safety and effectiveness of Loratadine in pediatric patients under 6 years of age have not been established.

Adverse Reactions

Claristine Tablets
Headache, Somnolence, Fatigue and Dry Mouth.

Claristine Syrup
Nervousness, Wheezing, Fatigue, Hyperkinesia, Abdominal Pain, Conjunctivitis, Dysphonia, Malaise, Upper Respiratory Tract Infection.

Autonomic Nervous system
Altered lacrimation, altered salivation, flushing, hypoesthesia, impotence, increased, sweating, thirst.

Body as a Whole
Angioneurotic edema, asthenia, back pain, blurred vision, chest pain, earache, eye pain, fever, leg cramps, malaise, rigors, tinnitus, viral infection, weight gain.

Cardiovascular System
Hypertension, hypotension, palpitations, supraventricular tachyarrhythmias, syncope, tachycardia,

Central and Peripheral Nervous System
Blepharospasm, dizziness, dysphonia, hypertonia, migraine, paresthesia, tremor, vertigo.

Gastrointestinal System
Altered taste, anorexia, constipation, diarrhea, dyspepsia, flatulence, gastritis, hiccup, increased appetite, nausea, stomtatitis, toothache, vomiting.

Musculoskeletal System
Arthralgia, myalgia.

Psychiatric
Agitation, amnesia, anxiety, confusion, decreased libido, depression, impaired concentration, insomnia, irritability, paranoia.

Reproductive System
Breast pain, dysmenorrhea, menorrhagia, vaginitis.

Respiratory System
Bronchitis, bronchospasm, coughing, dyspnea, epistaxis, hemoptysis, laryngitis, nasal dryness, pharyngitis, sinusitis, sneezing.

Skin and Appendages
Dermatitis, dry hair, dry skin, photosensitivity reaction, pruritus, purpura, rash, urticaria.

Urinary System
Altered micturition, urinary discoloration, urinary incontinence, urinary retention.

Drug Interactions
When administered concomitantly with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies.

Increase in plasma concentrations of loratadine have been reported after concomitant use with ketoconazole, erythromycin, or cimetidine, but without clinically significant changes (including electrocardiographic).

Laboratory Interference
Loratadine should be discontinued approximately 48 hours prior to skin testing procedures since antihistamines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

Dosage and Administration
Adults and children 12 years of age and over

The recommended dose of Claristine is 10 mg once daily.

Children 6-11 years of age
The recommended dose of Claristine is 10 mg (2 teaspoonfuls) once daily.
In patients with liver failure or renal insufficiency (GFR <30 ml/min), one tablet or two teaspoonfuls every other day should be the starting dose.

Over Dosage

Manifestation
In adults, somnolence, tachycardia, and headache have been reported with overdoses greater than 10 mg with the tablet formulation (40 to 180 mg) Extrapyramidal signs and palpitations have been reported in children with over-doses of greater than 10 mg of Loratadine syrup. In the event of over dosage, general symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary.

Treatment
Treatment of over dosage would reasonably consist of emesis (ipecac syrup), except in patients with impaired consciousness, followed by the administration of activated charcoal to absorb any remaining drug. If vomiting is unsuccessful, or contraindicated, gastric lavage should be performed with normal saline. Saline cathartics may also be *of* value for rapid dilution of bowel contents. Loratadine is not eliminated by hemodialysis. It is not known if Loratadine is eliminated by peritoneal dialysis.

Presentation

Claristine Tablets
Box of 10 tablets

Claristine Syrup
Bottle of 120 ml