LORVIC ®
(Loratadine Tablet/Syrup).

Composition:
Lorvic Tablet: Each tablet contains: Loratadine BP 10 mg.
Lorvic Syrup: Each 5ml contains: Loratadine 5 mg.
Pharmacology: Loratadine, the active ingredient in Loratadine 5mg/5ml Syrup, is a tricyclic antihistamine with selective, peripheral H1-receptor activity. Loratadine has no clinically significant sedative or anticholinergic properties in the majority of the population and when used at the recommended dosage. During long-term treatment there were no clinically significant changes in vital signs, laboratory test values, physical examinations or electrocardiograms. Loratadine has no significant H2-receptor activity. It does not inhibit norepinephrine uptake and has practically no influence on cardiovascular function or on intrinsic cardiac pacemaker activity.
Pharmacokinetics:
After oral administration, Loratadine is rapidly and well absorbed and undergoes an extensive first pass metabolism, mainly by CYP3A4 and CYP2D6. The major metabolite-desloratadine (DL)- is pharmacologically active and responsible for a large part of the clinical effect. Loratadine and DL achieve maximum plasma concentrations (Tmax) between 1-1.5 hours and 1.5-3.7 hours after administration, respectively. Increase in plasma concentrations of Loratadine has been reported after concomitant use with ketoconazole, erythromycin, and cimetidine in controlled trials, but without clinically significant changes. Loratadine is highly bound (97% to 99%) and its active metabolite moderately bound (73% to 76%) to plasma proteins. In healthy subjects, plasma distribution half-lives of Loratadine and its active metabolite are approximately 1 and 2 hours, respectively. The mean elimination half lives in healthy adult subjects were 8.4 hours (range=3 to 20 hours) for Loratadine and 28 hours (range-8.8 to 92 hours for the major active metabolite). Approximately 40% of the dose is excreted in the urine and 42% in the faeces over a 10 day period and mainly in the form of conjugated metabolites. Approximately 27% of the dose is eliminated in the urine during the first 24 hours. Less than 1% of the active substance is excreted unchanged in active form, as Loratadine or DL. The bioavailability parameters of Loratadine and of the active metabolite are dose proportional. The pharmacokinetic profile of Loratadine and its metabolites is comparable in healthy adult volunteers and in healthy geriatric volunteers. Concomitant ingestion of food can delay slightly the absorption of Loratadine but without influencing the clinical effect. In patients with chronic renal impairment, both the AUC and peak plasma levels (Cmax) increased for Loratadine and its metabolite as compared to the AUCs and peak plasma levels (Cmax) of patients with normal renal function. The mean elimination half-lives of Loratadine and its metabolite were not significantly different from that observed in normal subjects. Haemodialysis does not have an effect on the pharmacokinetics of Loratadine or its active metabolite in subjects with chronic renal impairment. In patients with chronic alcoholic liver disease, the AUC and peak plasma levels (Cmax) of Loratadine were double while the pharmacokinetic profile of the active metabolite was not significantly changed from that in patients with normal liver function. The elimination half-lives for Loratadine and its metabolite were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease. Loratadine and its active metabolite are excreted in the breast milk of lactating women.
Indications: Loratadine tablet/syrup is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticarial in adults and children over the age of 2 years.
Posology and method of administration:
Posology
Adults and children over 12 years of age: 10ml (10mg) of the syrup or one tablet once daily.
Paediatric population:
Children 2 to 12 years of age are dosed by weight:
Body weight more than 30kg: 10ml (10mg) of the syrup or one tablet once daily;
Body weight 30kg or less: 5ml (5mg) of the syrup once daily.
Children under 2 years of age: Not recommended since efficacy and safety has not been established.
Patients with severe liver impairment
Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine. An initial dose of 10mg every other day is recommended for adults and children weighing more than 30kg, and for children weighing 30kg or less, 5ml (5mg) every other day is recommended.
Patients with severe renal impairment: No dosage adjustments are required in the elderly or in patients with renal insufficiency.
Elderly: No dosage adjustments are required in the elderly.
Method of administration: For oral administration.
Contraindications: Contraindicated in patients who are hypersensitive to the active substance or to any of the excipients in this formulation.
Special warnings and precautions for use
Loratadine should be administered with caution in patients with severe liver impairment. Lorvic syrup contains sucrose; patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. The administration of Loratadine should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index.
Interaction with other medicinal products and other forms of interaction:
When administered concomitantly with alcohol, Loratadine has no potentiating effects as measured by psychomotor performance studies. Potential interaction may occur with all known inhibitors of CYP3A4 or CYP2D6 resulting in elevated levels of Loratadine which may cause an increase in adverse events. Increase in plasma concentrations of Loratadine has been reported after concomitant use with Ketoconazole, Erythromycin, and Cimetidine in controlled trials, but without clinically significant changes (including electrocardiographic).
Paediatric population: Interaction studies have only been performed in adults.
Fertility, pregnancy and lactation:
Pregnancy : A large amount of data on pregnant women (more than 1000 exposed outcomes) indicate no malformative nor feto/neonatal toxicity of Loratadine.Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Loratadine 5mg/5ml Syrup during pregnancy.
Breast-feeding: Loratadine is excreted in breast milk, therefore the use of Loratadine is not recommended in breast-feeding women.
Fertility: There are no data available on male and female fertility.
Effects on ability to drive and use machines:
In clinical trials that assessed driving ability, no impairment occurred in patients receiving Loratadine. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.
Adverse reactions: Most frequent adverse reactions includes; somnolence, headache, increased appetite, insomnia, headache, nervousness and fatigue. Other rare adverse reactions includes; Hypersensitivity reactions (including angioedema and anaphylaxis), dizziness, convulsion, tachycardia, palpitation, nausea, dry mouth, gastritis, abnormal hepatic function, rash, alopecia and fatigue.
Overdose:
Overdosage with Loratadine increased the occurrence of anticholinergic symptoms. Somnolence, tachycardia, and headache have been reported with overdoses. In the event of overdose, general symptomatic and supportive measures are to be instituted and maintained for as long as necessary. Administration of activated charcoal as a slurry with water may be attempted. Gastric lavage may be considered. Loratadine is not removed by haemodialysis and it is not known if Loratadine is removed by peritoneal dialysis. Medical monitoring of the patient is to be continued after emergency treatment.
Presentation: Lorvic Tablet: Blister pack of 3 x 10's in unit carton.
Lorvic Syrup: A well label Amber coloured bottle packed in a unit box.
Storage instructions: Store in a dry place, below 30°C. Protect from direct sunlight. Keep all medicines out of reach of children.
Manufactured By:

DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
P. O. Box 16633 – 00620, Nairobi, Kenya.

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