SUMMARY OF PRODUCT CHARACTERISTICS OF LORHISTINA SYRUP 5MG/5ML

1. Name of the medicinal product

Lorhisitna Syrup 5mg/5mL

2. Qualitative and quantitative composition

Each 5mL contains 5 mg of Loratadine.

3. Pharmaceutical form

Syrup

4. Clinical particulars

4.1 Therapeutic indications

Loratadine Syrup are indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

4.2 Posology and method of administration

Adults and children over 12 years of age:

10ml (10mg) of the oral solution once daily.

Paediatric population

Children 2 to 12 years of age ***are dosed by weight***:

Body weight more than 30kg: 10ml (10mg) of the oral solution once daily;

Body weight 30kg or less: 5ml (5mg) of the oral solution once daily.

Efficacy and safety of this medicine in children under 2 years of age has not been established.

Patients with hepatic 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 renal impairment

No dosage adjustments are required in the elderly or in patients with renal insufficiency.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Loratadine Syrup should be administered with caution in patients with severe liver impairment.

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

The administration of Loratadine Syrups should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index.

4.5 Interaction with other medicinal products and other forms of interaction

When administered concomitantly with alcohol, Loratadine Syrups have 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.

4.6 Pregnancy and lactation

Pregnancy

A large amount of data on pregnant women (more than 1000 exposed outcomes) indicate no malformative nor foeto/ 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 during pregnancy.

Breast-feeding

Loratadine is excreted in breast milk, therefore the use of loratadine is not recommended in breast-feeding women.

Fertility

There is no data available on male and female fertility.

4.7 Effects on ability to drive and use machines

In clinical trials that assessed driving ability, no impairment occurred in patients receiving Loratadine. Loratadine Syrups has no or negligible influence on the ability to drive and use machines. However, patients should be informed that very rarely some people experienced drowsiness, which may affect their ability to drive or use machines.

4.8 Undesirable effects

Immune system disorders	Very rare	Hypersensitivity reactions (including angioedema and anaphylaxis)
Nervous system disorders	Very rare	Dizziness, convulsion
Cardiac disorders	Very rare	Tachycardia, palpitation
Gastrointestinal disorders	Very rare	Nausea, dry mouth, gastritis
Hepato-biliary disorders	Very rare	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Very rare	Rash, alopecia
General disorders and administration site conditions	Very rare	Fatigue
Investigations	Not known	Weight increased

4.9 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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of action

Loratadine, the active ingredient in Loratadine Syrups, is a tricyclic antihistamine with selective, peripheral H_1-receptor activity.

Pharmacodynamic effects

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 H_2-receptor activity. It does not inhibit norepinephrine uptake and has practically no influence on cardiovascular function or on intrinsic cardiac pacemaker activity.

Human histamine skin wheal studies following a single 10 mg dose has shown that the antihistamine effects are seen within 1-3 hours reaching a peak at 8-12 hours and lasting in excess of 24 hours. There was no evidence of tolerance to this effect after 28 days of dosing with loratadine.

5.2 Pharmacokinetic properties

Absorption

Loratadine is rapidly and well-absorbed. Concomitant ingestion of food can delay slightly the absorption of loratadine but without influencing the clinical effect. The bioavailability parameters of loratadine and of the active metabolite are dose proportional.

Distribution

Loratadine is highly bound (97% to 99%) and its active major metabolite desloratadine (DL) 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.

Biotransformation

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.

Elimination

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.

5.3 Preclinical safety data

Non-Clinical data reveal no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

In reproductive toxicity studies, no teratogenic effects were observed. However, prolonged parturition and reduced viability of offspring were observed in rats at plasma levels (AUC) 10 times higher than those achieved with clinical doses.

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose BP

Sodium Benzoate BP

Propylene glycol BP

Glycerin BP

Citric acid anhydrous BP

Raspberry berry liquid flavour

6.2 Incompatibilities

None

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a dry place below 30˚C. Protect from Light.

6.5 Nature and contents of container

25mm mouth OD round amber clear glass bottles

6.6 Special precautions for disposal and other handling

No special requirements.

7 Registrant

Cosmos Limited

8 Manufacturer

Cosmos Limited

Rangwe Road; Off Lunga Lunga, Industrial Area

P.O Box 41433, GPO 00100-Nairobi

Kenya

Telephone: + (254-20) 2519603/4/5, 020 8042200/2/3/4/5

Telefax: +254-020-8096280/1

E-mail: admin@cosmos-pharm.com

Prepared by:

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Thomas Sila

R&D Assistant

Approved by:

.....

Dhruv Mandali.

R&D Head