1. NAME OF THE MEDICINAL PRODUCT

LORATADINE TABLETS USP 10MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Loratadine USP 10 mg

Each uncoated tablet contains:
Loratadine USP 10 mg
Excipients Q.S

3. PHARMACEUTICAL FORM

Oral uncoated tablet

4. Clinical particulars

4.1 Therapeutic indications

Loratadine oral solution is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticarial in adults and children over the age of 2 years.
It is also used in allergic rhinitis, Nasal Discharge and Itching, Ocular Itching and Burning Sneezing.

4.2 Posology and method ofadministration

Adults and children over 12 years of age:
10 mg once daily. The tablet may be taken without regard to mealtime.
Children 2 to 12 years of age:
Body weight more than 30 kg: 10 mg once daily.
Body weight 30 kg or less: These tablets are not suitable in children with a body weight less than 30 kg.
Efficacy and safety of Loratadine Tablets in children under 2 years of age has not been established.
Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of Loratadine. An initial dose of 10 mg every other day is recommended for adults and children weighing more than 30 kg, and for children weighing 30 kg or less, 5 ml (5 mg) every other day is recommended.
No dosage adjustments are required in the elderly or in patients with renal insufficiency.

- Recommended route of administration:Oral

4.3 Contraindications

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

4.4 Special warnings and precautions for use

This medicine should be administered with caution in patients with severe liver impairment.
This medicinal product 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 this medicine 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, this medicine 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

4.6 Pregnancy and Lactation

Pregnancy

A large amount of data on pregnant women (more than 1000 exposed outcomes) indicates no malformative or feto/neonatal toxicity of loratadine. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see As a precautionary measure, it is preferable to avoid the use of this medicine 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.

4.7 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.

4.8 Undesirable effects

Immune system disorders: Hypersensitivity reactions (including angioedema and anaphylaxis)
Very rare
Nervous system disorders: Dizziness, Convulsion
Very rare
Cardiac disorders: Tachycardia, palpitation
Very rare
Gastrointestinal disorders: Nausea, dry mouth, gastritis
Very rare
Hepato-biliary disorders: Abnormal hepatic function
Very rare
Skin and subcutaneous tissue disorders: Rash, alopecia
Very rare
General disorders and administration site conditions: Fatigue
Very rare.

Paediatric population

In clinical trials in a paediatric population children aged 2 through 12 years, common adverse reactions reported in excess of placebo were headache (2.7%), nervousness (2.3%), and fatigue (1%).

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 Pharmacodynamics properties

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.

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 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.
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. Less than 1% of the active substance is excreted unchanged in active form, as loratadine or DL.
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).

Renal impairment

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.
Hepatic 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.

Elderly

The pharmacokinetic profile of loratadine and its active metabolite is comparable in healthy adult volunteers and in healthy geriatric volunteers.
Loratadine and its active metabolite are excreted in the breast milk of lactating women.

5.3 Preclinical safety data

Preclinical data reveal no special hazard 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

Maize Starch
Lactose
Purified water

Purified Talc
Magnesium stearate
Colloidal anhydrous silica

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months for the date of manufacturing.

6.4 Special precautions for storage

Store below 30º C. Protect from light. Keep out of reach of children

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

10 X 10 Tablets in Alu-PVC Blister Pack

6.6 Special precautions for disposal <and other handling>

There are no special storage precautions. Any unused product or waste material should be disposed of in accordance with local requirements.

7. <APPLICANT/MANUFACTURER>

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