MECURE INDUSTRIES PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. NAME OF THE MEDICINAL PRODUCT

MeCure's Loratadine Tablets

(Loratadine BP 10 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:
Loratadine BP …….……10mg
Excipients……q.s.

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Tablet.

White colour oblong shape uncoated tablets with a break line on one side and the other side is plain.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Posology

A**dults 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 with: 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

Method of administration

For oral administration

4.3 CONTRAINDICATIONS

Conditions:

• Liver Failure, liver problems and moderate to severe kidney impairment

Allergies:
• Antihistamines
• Antihistamines – Piperidine

4.4 WARNING AND PRECAUTION

Loratadine Tablets 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 Tablets 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 Tablets 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 (see Section 5.2), which may cause an increase in adverse events.

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 (see section 5.3). 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 breastfeeding women.

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 experienced drowsiness, which may affect their ability to drive or use machines.

4.8 UNDESIRABLE EFFECTS

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%).
In clinical trials involving adults and adolescents in a range of indications including AR and CIU, at the recommended dose of 10 mg daily, adverse reactions with loratadine were reported in 2% of patients in excess of those treated with placebo. The most frequent adverse reactions reported in excess of placebo were somnolence (1.2%), headache (0.6%), increased appetite (0.5%) and insomnia (0.1%).

Immune system disorders	Hypersensitivity reactions (including angioedema and anaphylaxis)
Nervous system disorders	Dizziness, convulsion
Cardiac disorders	Tachycardia, palpitation
Gastrointestinal disorders	Nausea, dry mouth, gastritis
Hepato-biliary disorders	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Rash, alopecia
General disorders and administration site conditions	Fatigue
Adverse reactions with frequency 'not known:	
Investigations	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

Pharmacotherapeutic group: antihistamines – H1 antagonist, ATC code: R06A X13.
Loratadine, the active ingredient in Loratadine Tablets, 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.

5.2 Pharmacokinetic properties

After oral administration, loratadine is rapidly and well absorbed and undergoes 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 (including electrocardiographic).
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

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

Starch
Dicalcium phosphate
Starch
Gelatin
Propyl paraben
Methyl paraben
Magnesium stearate
Sodium starch glycolate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store in a cool dry place at temperature below 30°C
Keep this medicine out of the sight and reach of children.

6.5 Nature and contents of container

Available in blister packs of 10 x 10 tablets in a clinical carton.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER / MANUFACTURER

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Plot 6 Block H Debo Industries Compound,
Oshodi Industrial Scheme,
Oshodi,
Lagos,

Nigeria.