Clean amended proposed professional information for LORDYNO

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

LORDYNO tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg loratadine.

Excipient with known effect:

Contains sugar (69,175 mg lactose monohydrate per tablet).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

White, oval tablets, notched and coded LT/10 on one side (length: 7,5 to 7,9 mm and width: 4,9 to 5,3 mm).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LORDYNO is indicated for the relief of the symptoms associated with perennial and/or seasonal allergic rhinitis, chronic urticaria and other allergic skin disorders.

4.2 Posology and method of administration

Posology

Take one tablet once daily.

Method of administration

Oral administration.

LORDYNO can be taken with or without food.

4.3 Contraindications

- LORDYNO is contraindicated in patients who have shown hypersensitivity or idiosyncrasy to loratadine or to any of the excipients listed in section 6.1.
- Safety of LORDYNO in the elderly has not been established.

4.4 Special warnings and precautions for use

Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine, the active ingredient in LORDYNO; an initial dose of 5 mg once daily or 10 mg every second day is recommended.

Increase in body mass has been reported with the use of LORDYNO (see section 4.8).

LORDYNO contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption, should not take LORDYNO.

4.5 Interaction with other medicines and other forms of interaction

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

Loratadine, as in LORDYNO, is metabolised by cytochrome P450 isoenzymes CYP3A4 and CYP2D6. Concomitant administration of other medicines that inhibit or are metabolised by these hepatic enzymes may result in changes in the plasma concentrations of either medicine and, possibly, may have adverse effects.

Cimetidine, erythromycin, ketoconazole, quinidine, fluconazole and fluoxetine are all well known to inhibit one or more of these enzymes. Erythromycin, ketoconazole and cimetidine are all known to inhibit the metabolism of loratadine, as in LORDYNO. Similarly, clarithromycin inhibits the metabolism of loratadine, as in LORDYNO, and its active metabolite descarboethoxyloratadine.

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

4.6 Fertility, pregnancy and lactation

The safe use of LORDYNO during pregnancy or lactation has not been established.

4.7 Effects on ability to drive and use machines

LORDYNO lacks significant sedative effects. Patients should however be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. The effect may be compounded by the simultaneous intake of central nervous system depressants.

4.8 Undesirable effects

Summary of the safety profile

The most frequent adverse reactions are somnolence, headache, increased appetite and insomnia.

Tabulated list of adverse reactions

Immune system disorders:

Less frequent: Hypersensitivity reactions (including angioedema and anaphylaxis).

Metabolism and nutrition disorders:

Frequency unknown: Increased appetite, increased body mass.

Nervous system disorders:

Less frequent: Dizziness, convulsions, headache, somnolence, sedation, nervousness.

Cardiac disorders:

Less frequent: Tachycardia, palpitations.

Gastrointestinal disorders:

Less frequent: Nausea, dry mouth, gastritis.

Hepato-biliary disorders:

Less frequent: Abnormal hepatic function.

Skin and subcutaneous tissue disorders:

Less frequent: Rash, alopecia.

General disorders and administration site conditions:

Less frequent: Fatigue.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of LORDYNO is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to the South African Health Products Regulatory

Authority (SAHPRA) via the “Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Symptoms

Overdosage with LORDYNO increased the occurrence of anticholinergic symptoms. Somnolence, tachycardia and headache have been reported with overdose.

Treatment:

In the event of overdosage, treatment should be started immediately. Treatment is symptomatic and supportive.

Loratadine as in LORDYNO is not removed by haemodialysis and it is not known if it is removed by peritoneal dialysis. Medical monitoring of the patient is to be continued after emergency treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 5.7.1 Antihistaminics

Pharmacotherapeutic groups: Antihistamines – H1 antagonist

ATC codes: R06A X13.

Mechanism of action

Loratadine is a long-acting, tricyclic antihistamine with selective peripheral H_1-receptor antagonistic activity. Loratadine does not readily cross the blood-brain barrier.

5.2 Pharmacokinetic properties

Absorption

Loratadine is rapidly and well absorbed. Concomitant ingestion of food can slightly delay 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.

Maximal serum levels were achieved within 1,5 hours. Clinical effect was achieved within 2 hours.

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 (T_{max}) between 1 – 1,5 hours and 1,5 – 3,7 hours after administration, respectively.

Elimination

Excretion occurred equally via renal and faecal routes. 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.

Special populations:

Renal impairment

In patients with chronic renal impairment, both the AUC and peak plasma levels (C_{max}) increased

for loratadine and its metabolite as compared to the AUCs and peak plasma levels (C_{max}) of patients with normal renal function. The mean elimination half-lives of loratadine and its active 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 (C_{max}) 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 active metabolite were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease.

Elderly patients

The pharmacokinetic profile of loratadine and its active metabolite is comparable in healthy volunteers and in healthy geriatric volunteers.

5.3 Preclinical safety data

No further information of relevance available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal anhydrous silica

Lactose monohydrate

Magnesium stearate

Maize starch.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from excessive moisture.

6.5 Nature and contents of container

LORDYNO is packed into white, opaque PVC/aluminium blister strips containing 10 tablets each.

Pack sizes: 10, 30 or 250 tablets per carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biotech Laboratories (Pty) Ltd

Ground floor, Block K West, Central Park

400 16th Road, Randjiespark, Halfway House

Midrand 1685

8. REGISTRATION NUMBER

35/5.7.1/0355

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 15 November 2002

10. DATE OF REVISION OF THE TEXT

Submitted - June 2021

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