1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

LENAMET OTC (film-coated tablet)

COMPOSITION

Each film-coated tablet of LENAMET OTC contains 200 mg of cimetidine.

Excipients:

FD&C blue #2/indigo carmine (C.I. 73015:1), FD&C red #40/allura red AC aluminium lake (C.I. 16035:1), iron oxide yellow (C.I. 77492), lecithin (soya), macrogol, magnesium stearate, polyvinyl alcohol, povidone, purified talc, sodium starch glycollate, starch maize, titanium dioxide (C.I. 77891)

Sugar free

CATEGORY AND CLASS

A 11.4.3 Medicines acting on the gastrointestinal tract: Other

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Cimetidine is a histamine H_2-receptor antagonist. Its main action is to inhibit gastric acid secretion. It also inhibits competitively the other actions of histamine mediated by H_2-receptors. The decrease in gastric acid secretion occurs regardless of the nature of the

physiological stimulus to secretion, i.e. basal or unstimulated secretion, is reduced. Both the volume of secretion and the concentration of acid in the secretion are reduced.

INDICATIONS

For the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity.

CONTRAINDICATIONS

Hypersensitivity to cimetidine.

LENAMET OTC is not recommended for minor digestive complaints. It is also not recommended for patients with impaired renal function.

Pregnancy and lactation.

LENAMET OTC should not be taken by:

- Patients suffering from any other illness or taking any other medications unless prescribed by a doctor.
- Patients middle-aged or older with new or recently changed dyspeptic symptoms - consult a doctor.
- Patients suffering from dyspepsia, with unintended weight loss - consult a doctor.

WARNINGS AND SPECIAL PRECAUTIONS

Patients must seek medical advice if:

- Symptoms fail to respond;
- symptoms persist after 2 weeks treatment;
- symptoms recur following self treatment.

INTERACTIONS

- Antacids - simultaneous administration of medium to high potency antacids (80 mmol to 150 mmol HCI neutralising capacity) may decrease the absorption of LENAMET OTC.
- Metoclopramide - may reduce the bioavailability of LENAMET OTC due to reduction of gastrointestinal transit time.
- Propantheline - has been reported to reduce the bioavailability of LENAMET OTC by reducing the intestinal motility.
- The following medicines may be affected by LENAMET OTC due to its inhibition of the cytochrome P-450 enzyme system resulting in decreased hepatic metabolism of these medications with increased blood concentrations and delayed elimination: Cyclosporin, lignocaine, nifedipine, phenytoin, suxamethonium, theophylline, warfarin, quinidine, phenobarbital, many benzodiazepines i.e. chlordiazepoxide, diazepam and midazolam, propranolol, digitoxin, mexiletine and tricyclic anti-depressants such as imipramine. Dosage regimes should be reduced or altered accordingly.

HUMAN REPRODUCTION

LENAMET OTC should not be used during pregnancy and lactation (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Clinical experience with LENAMET OTC in children is limited. Therefore LENAMET OTC therapy cannot be recommended for children.

Adults and children aged 16 years and older:

Take one tablet 3 times a day with meals and at bedtime for a maximum period of two weeks (maximum daily dose of 800 mg). Do not exceed the maximum daily dosage of

800 mg.

Do not take for longer than 2 weeks without consulting your doctor, since persistent symptoms may indicate other medical problems.

Do not take more than four tablets in a period of 24 hours.

Patients must seek medical advice if: symptoms fail to respond; symptoms persist after 2 weeks treatment; symptoms recur following self treatment.

SIDE EFFECTS

Diarrhoea, dizziness, tiredness, headache and rashes or pruritis are most common.

Other side effects rarely reported include hypersensitivity reactions and fever, arthralgia and myalgia, blood disorders including agranulocytosis, neutropenia, leucopenia, pancytopenia and thrombocytopenia, interstitial nephritis, hepatotoxicity, bradycardia, atrioventricular block, tachycardia and hypotension.

Reversible confusional states and brainstem syndrome (with ataxia, dysarthria, visual impairment, deafness and paraesthesia), coma, convulsions, encephalopathy, visual hallucinations, paranoia, chorea, myopathy and neuropathy especially in the elderly or in seriously ill patients i.e. those with renal failure, have occurred less frequently.

LENAMET OTC has a weak anti-androgenic effect and gynaecomastia and impotence have also occasionally occurred in men receiving relatively high doses for conditions such as the Zollinger-Ellison Syndrome (1 000 mg/day to 1 600 mg/day).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

See SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS.

Treatment is symptomatic and supportive.

IDENTIFICATION

A pale green film-coated shallow biconvex tablet, engraved with “LENAMET 200” on one side and plain on the other side.

PRESENTATION

10, 20 or 50 tablets are packed in a clear polyvinylchloride film sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton.

Not all pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C, in a cool place.

Protect from light.

Keep the blisters in the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

30/11.4.3/0412

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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