OM CAPSULES
(OMEPRAZOLE 20MG)

1.6 Product Information

1.6.1 Prescribing information (Summary of Product Characteristics)

1. Name of the medicinal product

OM capsules

2. Qualitative and quantitative composition

Each capsule contains Omeprazole BP 20mg

3. Pharmaceutical form

Capsule

4. Clinical Particulars

4.1 Therapeutic Indications

4.2 Posology and method of administration

Omeprazole is given by mouth as capsules containing enteric coated pellets or granules which should be swallowed whole and not crushed or chewed. In patients with swallowing difficulties, it is recommended that the contents of the capsules be mixed with a little water, fruit juice or yoghurt and swallowed. Omeprazole maybe given by mouth as the-base or the magnesium salt. Doses are expressed in the terms of the base.

For the relief of acid-related dyspepsia Omeprazole is given in usual doses of 10 to 20 mg daily by mouth for 2 to 4 weeks.

4.3 Contraindications

It is used in conditions where inhibition of gastric acid secretion may be beneficial, including aspiration syndromes, dyspepsia, gastro-oesophageal reflux disease, peptic ulcer disease and the Zollinger-Ellison syndrome

4.4 Special Warnings and Precautions for Use

Before giving Omeprazole to patients with gastric ulcers the possibility of malignancy should be considered since Omeprazole may mask symptoms and delay diagnosis. Omeprazole is extensively metabolised in the liver and dosage should be reduced in hepatic impairment.

4.5 Interaction with other medicinal products and other forms of Interaction

Omeprazole contains a sulfinyl group in the bridge that links substituted benzimidazole and pyridine rings. Omeprazole is chemically stable and devoid of inhibitory activity at neutral pH. However the compound is protonated at pH 5 and below and rapidly rearranges to two species, a sulphuric acid and a sulphenamide, that react with sulfhydryl groups in the enzyme. Complete inhibition occurs when two reactive molecules derived from omeprazole are bound to each molecule of enzyme through disulfide linkages.

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The selective distribution of the (H/K ATPase) and the requirement for an acidic environment to generate the active forms of omeprazole lend a high degree of specificity to its actions. The active species are permanent cations and are concentrated within the highly acidic lumen of the parietal cell canaliculi adjacent to the luminal face of the target enzyme.

4.6 Pregnancy and Lactation

Pregnancy

Results from three prospective epidemiological studies (more than 1000 exposed outcomes) indicate no adverse effects of omeprazole on pregnancy or on the health of the foetus /newborn child. Omeprazole can be used during pregnancy**.**

Breast-feeding

Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are use

4.7 Effects on Ability to Drive and Use Machines

None unknown

4.8 Undesirable Effects

Adverse effects reported most frequently with Omeprazole and other proton pump inhibitors have been headache, diarrhoea and skin rashes, they have sometimes been severe enough to require discontinuation of treatment. Other effects include pruritus, dizziness, fatigue, constipation, nausea and vomiting, flatulence, abdominal pain, arthralgia, myalgia, urticaria and dry mouth, Isolated cases of photosensitivity, bullous eruption, erythema multiforme, angioedema and anaphylaxis have been reported. Effects on the CNS include occasional insomnia, somnolence and vertigo, reversible confusional states, agitation, depression and hallucinations have occurred in severely ill patients, raised liver enzymes and isolated cases of hepatitis, jaundice and hepatic encephalopathy have been reported. Other adverse effects reported rarely or in isolated cases include paraesthesia, blurred vision, alopecia, stomatitis, taste disturbances, peripheral oedema, hyponatraemia, blood disorders (including agranulocytosis, leucopenia, and thrombocytopenia) and interstitial nephritis. Proton pump inhibitors may increase the risk of gastrointestinal infections because of their acid suppressive effects. .

STORAGE: Store in a dry place at a temperature not exceeding 30°C. Keep unprotected capsules in a well closed container out of reach of children. Protect from light.

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4.9 Overdose and treatment

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The usual dose for the treatment of gastro-oesophageal reflux disease is 20 mg by mouth once daily for 4 weeks, followed by a further 4 to 8 weeks if not fully healed. In refractory oesophagitis, a dose of 40 mg daily may be used. Maintenance therapy after healing of oesophagitis is 20 mg once daily and for acid reflux is 10 mg daily in children. Doses in the range 0.7 to 1.45 mg per kg body weight daily up to a maximum daily dose of 40 mg, have been given for 4 to 12 weeks. In the management of peptic ulcer disease a single daily dose of 20 mg by mouth or 40 mg in severe cases is given. Treatment is continued for 4 weeks for duodenal ulcer and 8 weeks for gastric ulcer. Where appropriate, a dose of 10 to 20 mg once daily may be given for maintenance.

For the eradication of Helicobacter pylori in peptic ulceration Omeprazole may be combined with antibacterial in dual or triple therapy. Effective triple therapy regimens include Omeprazole 20 mg twice daily combined with Amoxycillin 500 mg and Metronidazole 400 mg both three times daily; Clarithromycin 500 mg and Metronidazole 400 mg (or Tinidaxole 500 mg) both twice daily; or with Amoxycillin 1g and Clarithromycin 500 mg both twice daily. These regimens are given for 4 week. Dual therapy regimens such as Omeprazole 40 mg daily with either Amoxycillin 750 mg to 1 g twice daily or Clarithromycin 500 mg three times daily are less effective and must be given for 2 weeks, Omeprazole alone may be continued for a further 2 to 8 weeks. Doses of 20 mg daily are used in the treatment of NSAID-associated ulceration; a dose of 20 mg daily may also be used for prophylaxis in patients with previous history of gastroduodenal lesions who require continued NSAID treatment. The initial recommended dosage for patients with the Zollinger-Ellison Syndrome is 60 mg by mouth once daily, adjusted as required. The majority of patients are effectively controlled by doses in the range of 20 to 120 mg daily but doses up to 120 mg three times daily have been used. Daily doses above 80 mg should be administered in divided doses (usually 2). Omeprazole is also used for the prophylaxis of acid aspiration during general

anaesthesia in a dose of 40 mg the evening before surgery and a further 40 mg two to six hours before the procedure.

DOSAGE IN HEPATIC IMPAIRMENT:

Consideration should be given to reducing the dose of Omeprazole in patients with impaired hepatic function. Dose adjustment should be considered particularly where maintenance treatment is required.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The pharmacological effects of Omeprazole are largely confined to inhibition of gastric acid secretion and effects that result there from, Omeprazole produces only small and inconsistent changes in the volume of gastric juice or in the secretion of pepsin and intrinsic factor, gastric motility is not affected, Omeprazole produces a dose-related inhibition of gastric acid secretion that persists after the drug disappears from the plasma. Given in sufficient dosage, Omeprazole can reduce daily production of acid by more than 95%; pre-treatment values are not achieved until 4 to 5 days after withdrawal of the drug, presumably reflecting the time required to synthesize the protein. One consequence of profound reduction in gastric acidity is increased secretion of gastrin and patients who take the usual therapeutic dose of Omeprazole have a modest hypergastrinaemia. Prolonged administration of very high _ doses of Omeprazole to experimental animals causes hyperplasia of oxyntic mucosal cells, presumably because of trophic effects of gastrin on these cells; carcinoid tumours are also produced in rats. There is no evidence of mucosal proliferation in human subjects though care should be taken if Omeprazole is to be administered for more than 8 weeks.

5.2 Pharmacokinetic properties

Omeprazole is rapidly but variably absorbed following oral administration. Absorption is not affected by food. Omeprazole is acid-labile and pharmacokinetics may vary between the various formulations developed to improve oral bioavailability. The absorption of omeprazole also appears to be dose-dependent; increasing the dosage above 40 mg has been reported to increase the plasma concentrations in a non-linear fashion because of saturable first pass hepatic metabolism. In addition, absorption is higher after long term administration.

Bioavailability of Omeprazole may be increased in elderly patients, in some ethnic groups such as Chinese and in patients with impaired hepatic function but is not markedly affected in

patients with renal impairment. Following absorption, Omeprazole is almost completely metabolised in the liver, primarily by the cytochrome P450 isoenzyme (CYP2C19) to form Omeprazole sulfone. The metabolites are inactive and are excreted mostly in urine and to a lesser extent in bile. The elimination half-life from plasma is reported to be about 0.5 to 3 hours. Omeprazole is highly bound (about 95%) to plasma proteins.

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

Empty gelatin capsule pink Transparent /Transparent –Size "2"

6.2 Incompatibilities

None known.

6.3 Shelf Life

36 months from the date of manufacture

6.4 Special Precautions for Storage

Store below 30°C in a dry place.

6.5 Nature and Contents of Container

BLISTER PACKS:

Packed in blisters of 10x10 in a unit box, 1000's in HDPE container with literature insert

6.6 Special precaution for disposal and other handling

Not applicable

7 Marketing Authorization Holder and Manufacturing Site Addresses
Marketing Authorization Holder:

Company Name: LABORATORY & ALLIED LTD

Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa road, P.O. Box 42875 GPO 00100, Nairobi,

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E-Mail : info@laballied.com

8 Marketing Authorization Number:
KENYA:

9 Date of first Registration/ Renewal of the Registration:
KENYA: 2013

10 Date of revision of the text:
April 2019