SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. Name of the medicinal product

OPRAZ (OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20 MG)

2. Qualitative and quantitative composition

OPRAZ (OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20 MG)

Each hard gelatin capsule contains:

Omeprazole .....20 mg

For full list of excipients, see section 6.1

3. Pharmaceutical form

Hard gelatin capsule

Hard gelatin capsule of size '2' having peach coloured cap and white coloured body containing white coloured pellets.

4. Clinical particulars

4.1 Therapeutic indications

Treatment of reflux oesophagitis disease. In reflux oesophagitis the majority of patients are healed after 4 weeks. Symptom relief is rapid.

Treatment of duodenal and benign gastric ulcers including complicating NSAID therapy.

Relief of reflux-like symptoms (e.g. heartburn) and/or ulcer-like symptoms (e.g. epigastric pain) associated with acid-related dyspepsia.

Treatment and prophylaxis of NSAID-associated benign gastric ulcers, duodenal ulcers and gastroduodenal erosions in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment.

Relief of associated dyspeptic symptoms.

Helicobacter pylori eradication: When used with in combination with antibiotics, Omeprazole proves effective in the eradication of Helicobacterpylori (Hp) in peptic ulcer disease.

Prophylaxis of acid aspiration.

Zollinger-Ellison syndrome.

4.2 Posology and method of administration

Average dose and dose range for adults and children

Peptic ulcer:

Adult: 20 mg daily as a single dose or 40 mg daily in severe cases. Treatment duration: Duodenal ulcers: 4 wk; gastric ulcers: 8 wk. Maintenance: 10-20 mg once daily.

NSAID-associated ulceration

Adult: 20 mg daily. Same dose may also be used for prophylaxis of ulceration in patients who require continued NSAID therapy.

H.pylori infection:

Adult: Dose varies with regimen. As triple therapy: 20 mg bid or 40 mg once daily; requires combination therapy with antibiotics. Therapy is given for 1 wk. Omeprazole may be continued for another 4-8 wk on its own.

Gastro-oesophageal reflux disease:

Adult: 20 mg once daily for 4 wk, may continue for another 4-8 wk if necessary. Maintenance: 10 mg daily.

Child: Neonate, 1 mth-2 yr: 700 mcg/kg/day, may increase up to 3 mg/kg/day, or 20 mg daily. >2 yr: <20 kg: 10 mg once daily; ≥20 kg: 20 mg

daily. Doses may be doubled if necessary.

Zollinger-Ellison syndrome:

Adult: Initially, 60 mg once daily, adjust according to response. Maintenance: 20-120 mg daily. Doses >80 mg are administered usually in 2 divided doses.

Prophylaxis of acid aspiration during general anaesthesia:

Adult: Initially, 40 mg given the evening before surgery and another 40 mg 2-6 hr before the procedure.

Acid-related dyspepsia:

Adult: 10 or 20 mg daily for 2-4 wk.

Erosive oesophagitis:

Adult: 20 mg/day for 4-8 wk. Maintenance of healing: 20 mg/day for up to 12 mth of total therapy (including treatment period).

Dosage interval

Omeprazole is prescribed for the short-term treatment (4 to 8 weeks) of the following: Stomach ulcer.

Duodenal ulcer (near the exit from the stomach)

Erosive Esophagitis (inflammation of the esophagus).

Average duration of treatment

By mouth being gastric & duodenal ulcers, 20 mg once daily for 4 weeks in duodenal ulceration or 8 weeks in gastric ulceration; in severe or recurrent cases increase to 40 mg daily maintenance for recurrent duodenal ulcer, 20 mg once daily; prevention of relapse in duodenal ulcer, 10 mg daily increasing to 20 mg once daily if symptoms return NSAID-associated duodenal or gastric ulcer or gastro duodenal erosion, 20 mg once daily for 4 weeks, followed by a further 4 weeks if not fully healed; prophylaxis in patients with a history of NSAID-associated duodenal or gastric ulcer, gastro duodenal lesions, dyspeptic symptoms who require continued NSAID treatment, 20 mg once daily benign gastric ulcer associated with H.pylori, Omeprazole 40 mg daily in 12 divided doses (plus amoxicillin 0.751 g twice daily) for 2 weeks Zollinger Ellison syndrome. Initially 60 mg dose daily; usual range 20120 mg daily (above 80 mg in divided doses) Gastric acid reduction during general anesthesia (prophylaxis of acid aspiration), 40 mg on the preceding evening then 40 mg 26 hours before surgery gastro-esophageal reflux disease, 20 mg once daily for 4 weeks, followed by a further 48 weeks if not fully healed; 40 mg once daily has been given for 8 weeks, in gastro-esophageal reflux disease refectory to other treatment may be continued at 20 mg once daily acid reflux disease (long term management) 10 mg daily increasing to 20 mg once daily if symptoms return. Acid related dyspepsia10, 20 mg once daily for 24 weeks according to response. Child over 2 years severe ulcerating reflux Oesophagitis, 0.71.4 mg/kg daily for 412 weeks; max. 40 mg daily (to be initiated by hospital pediatrician) Benign gastric ulcer, duodenal ulcer and gastro-esophageal reflux, 40 mg once daily until oral administration possible Child not recommended.

4.3 Contraindications

Omeprazole Delayed-Release Capsules are contraindicated in patients with known hypersensitivity to any component of the formulation.

4.4 Special warnings and precautions for use

Decreased gastric acidity due to any means, including proton-pump inhibitors, increases gastric counts of bacteria normally present in the gastrointestinal tract.

Treatment with acid-reducing drugs may lead to a slightly increased risk of gastrointestinal infections, such as Salmonella and Campylobacter.
This product contains sucrose and therefore patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the decreased intragastric acidity the absorption of ketoconazole or itraconazole may be reduced during omeprazole treatment as it is during treatment with other acid secretion inhibitors.
As omeprazole is metabolised in the liver through cytochrome P450, it can prolong the elimination of diazepam, phenytoin and warfarin. Monitoring of patients receiving warfarin or phenytoin is recommended and a reduction of warfarin or phenytoin dose may be required. However, concomitant treatment with Omeprazole 20 mg once daily did not change the blood concentration of phenytoin in patients on continuous treatment with phenytoin. Similarly, concomitant treatment with Omeprazole 20 mg daily did not change coagulation time in patients on continuous treatment with warfarin.
Plasma concentrations of omeprazole and clarithromycin are increased during concomitant administration. This is considered to be a useful interaction during H. pylori eradication. There is no interaction with metronidazole or amoxicillin.
These antimicrobials are used concomitantly with omeprazole for the eradication of H. pylori.
There is no evidence of an interaction with phenacetin, theophylline, caffeine, propranolol, metoprolol, ciclosporin, lidocaine, quinidine, estradiol, or antacids.
The absorption of Omeprazole 20 mg Capsules is not affected by alcohol or food.
There is no evidence of an interaction with piroxicam, diclofenac or naproxen.
This is considered useful when patients are required to continue these treatments.
Simultaneous treatment with omeprazole and digoxin in healthy subjects lead to a 10% increase in the bioavailability of digoxin as a consequence of the increased intragastric ph.

4.6 Fertility, Pregnancy and lactation

Pregnancy

Several studies have reported no apparent adverse short-term effects on the infant when single dose oral or intravenous omeprazole was administered to over 200 pregnant women as premedication for cesarean section under general anesthesia.

Nursing Mothers

Omeprazole concentrations have been measured in breast milk of a woman following oral administration of 20 mg. The peak concentration of omeprazole in breast milk was less than 7% of the peak serum concentration. This concentration would correspond to 0.004 mg of omeprazole in 200 mL of milk. Because omeprazole is excreted in human milk, because of the potential for serious adverse reactions in nursing infants from omeprazole, and because of the potential for tumorigenicity shown for omeprazole in rat carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Omeprazole 20 mg Capsules are well tolerated and adverse reactions have generally been mild and reversible. The following have been reported as adverse events in clinical trials or reported from routine use but in many cases a relationship to treatment with omeprazole has not been established.

The following definitions of frequencies are used:

Common ≥ 1/100, Uncommon ≥ 1/1000 and < 1/100, Rare < 1/1000

Common	Central and peripheral nervous system: Gastrointestinal:	Headache Diarrhoea, constipation, abdominal pain, nausea/vomiting and flatulence.
Uncommon	Central and peripheral nervous system: Hepatic: Skin: Other:	Dizziness, paraesthesia, light headedness, feeling faint, somnolence, insomnia and vertigo Increased liver enzymes Rash and/or pruritis Urticaria Malaise

Rare	Central and peripheral nervous system:	Reversible mental confusion, agitation, aggression, depression and hallucinations, predominantly in severely ill patients.
	Endocrine:	Gynaecomastia.
	Gastrointestinal:	Dry mouth, stomatitis, and gastrointestinal candidiasis.
	Haematological:	Leukopenia, thrombocytopenia, Agranulocytosis and pancytopenia.
	Hepatic:	Encephalopathy in patients with pre-existing severe liver disease; hepatitis with or without jaundice, hepatic failure.
	Musculoskeletal:	Arthritic and myalgic symptoms and muscular weakness.
	Reproductive system and breast disorders	Impotence.
	Skin:	Photosensitivity, bullous eruption erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, alopecia.
	Other:	Hypersensitivity reactions e.g. angioedema, fever, bronchospasm, interstitial nephritis and anaphylactic shock. Increased sweating, peripheral oedema, blurred vision, taste disturbance and Hyponatraemia.

Reporting of Suspected Adverse Reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system. This is the national reporting sytem : Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Rare reports have been received of overdosage with omeprazole. Doses of up to 560 mg have been described and occasional reports have been received when single oral doses have been reached up to 2400 mg, which is 120 times the recommended clinical dose. Overdosage of omeprazole is reported to be associated with nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache. Single cases of apathy, depression and confusion have been described.

The symptoms described in connection with omeprazole overdosage have been transient and no serious outcome has been reported. The rate of elimination was unchanged (first order kinetics) with increased doses and no specific treatment is needed.
Treatment of over dosage: Treatment is supportive; not dialyzable.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Proton pump inhibitors
ATC Code - A02BC01
Omeprazole is a racemate. It contains a tricoordinated sulfur atom in a pyramidal structure and therefore can exist in equal amounts of both the S and R enantiomers. In the acidic conditions of the stomach, both are converted to achiral products, which reacts with a cysteine group in H+/K+ ATPase, thereby inhibiting the ability of the parietal cells to produce gastric acid.
Mechanism of action:
Omeprazole belongs to a class of antisecretory compounds, the substituted benzimidazoles, that suppress gastric acid secretion by specific inhibition of the H+/K+ ATPase enzyme system at the secretory surface of the gastric parietal cell. Because this enzyme system is regarded as the acid (proton) pump within the gastric mucosa, Omeprazole has been characterized as a gastric acid-pump inhibitor, in that it blocks the final step of acid production. This effect is dose-related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus. Animal studies indicate that after rapid disappearance from plasma, Omeprazole can be found within the gastric mucosa for a day or more.

5.2 Pharmacokinetic properties

Absorption and distribution
Omeprazole is acid labile and is administered orally as enteric-coated granules in capsules. Absorption takes place in the small intestine and is usually completed within 3 – 6 hours. The systemic bioavailability of omeprazole from a single oral dose is approximately 35%. After repeated once-daily administration, the bioavailability increases to about 60%. Concomitant intake of food has no influence on the bioavailability. The plasma protein binding of omeprazole is about 95%.

Elimination and metabolism

The average half-life of the terminal phase of the plasma concentration-time curve is approximately 40 minutes. There is no change in half-life during treatment. The inhibition of acid secretion is related to the area under the plasma concentration-time curve (AUC) but not to the actual plasma concentration at a given time.

Omeprazole is entirely metabolised, mainly in the liver. Identified metabolites in plasma are the sulfone, the sulfide and hydroxy-omeprazole, these metabolites have no significant effect on acid secretion. About 80% of the metabolites are excreted in the urine and the rest in the faeces. The two main urinary metabolites are hydroxy-omeprazole and the corresponding carboxylic acid.

The systemic bioavailability of omeprazole is not significantly altered in patients with reduced renal function. The area under the plasma concentrationtime curve is increased in patients with impaired liver function, but no tendency to accumulation of omeprazole has been found.

5.3 Preclinical safety data

Gastric ECL-cell hyperplasia and carcinoids, have been observed in life-long studies in rats treated with omeprazole. These changes are the result of sustained hypergastrinaemia secondary to acid inhibition. Similar findings have been made after treatment with H2- receptor antagonists, proton pump inhibitors and after partial fundectomy. Thus, these changes are not from a direct effect of any individual drug.

6. Pharmaceutical particulars

6.1 List of excipients

Not applicable

6.2 Incompatibilities

None reported

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C.

Protect from light and moisture.

Keep medicine out of reach of children.

6.5 Nature and contents of container

Alu-Alu Strip pack of 10 x 10 Capsules

6.6 Special precautions for disposal and other handling

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

7. Marketing authorisation holder

Galaxy Pharmaceuticals
P.O. Box 39107- 00623.
Nairobi, Kenya

Manufacturer:

FREDUN PHARMACEUTICALS LTD.
14, 15, 16, Zorabian lndustrial Complex,
Vevoor, Palghar(E)-401 404.INDIA

8. Marketing authorisation number (s)

H2006/456

9. Date of first authorisation/renewal of the authorisation

07th March 2018

10. Date of revision of the text

01/2026, 18th August 2026