Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Esomod 20
(Esomeprazole Tablets 20 mg)

2. Qualitative and quantitative composition

Each enteric coated tablet contains:
Esomeprazole Magnesium Trihydrate USP
Eq. to Esomeprazole ..... 20 mg
Excipients ..... q.s.
Colour: Red Oxide of Iron & Titanium Dioxide

Excipient(s) of known effect: Sodium (present as sodium carbonate anhydrous, sodium lauryl sulfate and sodium starch glycolate).

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Enteric coated tablet.
Brick coloured, round shaped enteric coated tablets, plain on both sides.

4. Clinical particulars

4.1 Therapeutic indications

Esomod 20 is indicated for the treatment of gastroesophageal reflux disease (GERD), including erosive oesophagitis and symptomatic relief of GERD. It is also indicated, in combination with appropriate antibiotics, for the eradication of Helicobacter pylori and prevention of relapse of H. pylori-associated peptic ulcers, for the healing of NSAID-associated gastric ulcers and prevention of NSAID-associated gastric and duodenal ulcers in patients at risk, and in the management of Zollinger-Ellison syndrome.

4.2 Posology and method of administration

Posology

Adults

Gastroesophageal Reflux Disease (GERD)

Treatment of erosive reflux oesophagitis:

40 mg once daily for 4 weeks. An additional 4 weeks of treatment is recommended if the oesophagitis has not healed or if symptoms persist.

Long-term management of healed oesophagitis (prevention of relapse):

20 mg once daily.

Symptomatic treatment of GERD (without oesophagitis):

20 mg once daily in patients without oesophagitis. If symptom control has not been achieved after 4 weeks, the patient should be further investigated. Once symptoms have resolved, subsequent symptom control can be achieved using an on-demand regimen of 20 mg once daily

as required. On-demand use is not recommended in patients concomitantly taking NSAIDs.

Helicobacter pylori Eradication and Prevention of Relapse of Duodenal Ulcers
For eradication of H. pylori and healing/prevention of relapse of H. pylori-associated duodenal ulcers, Esomod 20 should be given as part of an appropriate combination antibacterial therapy, for example:

Medicinal product	Dose	Frequency	Duration
Esomeprazole	20 mg	Twice daily	7 days
Amoxicillin	1 g	Twice daily	7 days
Clarithromycin	500 mg	Twice daily	7 days

NSAID-Associated Ulcers
Healing:
20 mg once daily for 4-8 weeks.
Prevention:
20 mg once daily.

Prevention of Rebleeding of Peptic Ulcers Following Therapeutic Intravenous Esomeprazole
Following intravenous therapy for prevention of rebleeding of peptic ulcers, 40 mg once daily orally for 4 weeks.

Zollinger-Ellison Syndrome
The recommended starting dose is 40 mg twice daily. The dose should thereafter be adjusted individually and treatment continued for as long as clinically indicated; doses of up to 80 mg twice daily have been used. If the daily dose exceeds 80 mg, it should be divided and given twice daily.

Special populations
Renal impairment:
No dose adjustment is needed in patients with renal impairment. Due to limited experience, caution should be exercised in patients with severe renal insufficiency.
Hepatic impairment:
No dose adjustment is necessary in patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment, a maximum dose of 20 mg once daily should not be exceeded.
Elderly:
No dose adjustment required.

Paediatric population
Adolescents 12 years and older
Gastroesophageal Reflux Disease (GERD):
Treatment of erosive reflux oesophagitis: 40 mg once daily for 4 weeks; an additional 4 weeks is recommended if not healed or if symptoms persist. Long-term management of healed oesophagitis: 20 mg once daily.

Symptomatic treatment of GERD: 20 mg once daily; reassess if no improvement after 4 weeks.

Helicobacter pylori-Associated Duodenal Ulcer:

To be used as part of appropriate combination antibacterial therapy for eradication of H. pylori, under specialist supervision.

Method of administration

The tablets should be swallowed whole with liquid. The tablets should not be chewed or crushed.

For patients who have difficulty swallowing, the tablets can be dispersed in half a glass of non-carbonated water. No other liquids should be used, as the enteric coating may dissolve. Stir until the tablets disintegrate and drink the liquid with the pellets immediately or within 30 minutes. Rinse the glass with half a glass of water and drink. The pellets must not be chewed or crushed.

For patients who cannot swallow, the tablets can be dispersed in non-carbonated water and administered through a gastric tube. The appropriateness of the selected syringe and tube must be carefully tested before use.

4.3 Contraindications

Hypersensitivity to esomeprazole, substituted benzimidazoles, or to any of the excipients listed in section 6.1.

Esomeprazole should not be used concomitantly with nelfinavir.

4.4 Special warnings and precautions for use

Alarm symptoms

In the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melaena) and when a gastric ulcer is suspected or present, malignancy should be excluded, as treatment with esomeprazole may alleviate symptoms and delay diagnosis.

Long-term use

Patients on long-term treatment (particularly those treated for more than a year) should be kept under regular surveillance.

On-demand treatment

Patients should be instructed to contact their doctor if their symptoms change while on on-demand therapy.

Helicobacter pylori eradication

The potential for drug interactions should be considered for all components of triple therapy, in particular clarithromycin, which is a potent inhibitor of CYP3A4.

Gastrointestinal infections

Treatment with proton pump inhibitors may lead to a slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter.

Absorption of vitamin B12

Esomeprazole, as with all acid-blocking medicinal products, may reduce absorption of vitamin B12 during long-term treatment, especially in patients at risk of reduced vitamin B12 absorption.

Hypomagnesaemia
Severe hypomagnesaemia has been reported in patients treated with proton pump inhibitors, including esomeprazole, for at least three months. Physicians should consider measuring magnesium levels before starting long-term treatment and periodically during treatment, particularly in patients also taking digoxin or medicinal products that may cause hypomagnesaemia (e.g. diuretics).
Risk of fracture
Proton pump inhibitors, especially at high doses and over long durations (more than 1 year), may be associated with a modestly increased risk of hip, wrist and spine fracture, predominantly in the elderly or in the presence of other recognised risk factors.
Subacute cutaneous lupus erythematosus (SCLE)
Proton pump inhibitors, including esomeprazole, are associated with very rare cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, treatment should be discontinued promptly and the patient advised to avoid sun exposure.
Concomitant use with other medicinal products
Concomitant use of esomeprazole with atazanavir is not recommended. Interactions with medicinal products metabolised via CYP2C19, such as clopidogrel, should be monitored, as esomeprazole may reduce clopidogrel exposure; the clinical relevance is not fully established, and use of on-demand esomeprazole may also affect this interaction.
Serious cutaneous adverse reactions (SCARs)
Serious cutaneous adverse reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported rarely in association with esomeprazole. Esomeprazole should be discontinued at the first appearance of signs and symptoms of serious skin reactions, and the patient should not be re-challenged.
Sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.
Interference with laboratory tests
Increased Chromogranin A (CgA) levels may interfere with investigations for neuroendocrine tumours. To avoid this interference, esomeprazole treatment should be stopped for at least 5 days before CgA measurements.

4.5 Interaction with other medicinal products and other forms of interaction

Effects of esomeprazole on the pharmacokinetics of other medicinal products
Protease inhibitors
Esomeprazole may reduce plasma levels of atazanavir and nelfinavir due to its effect on gastric pH and CYP2C19 inhibition. Co-administration of esomeprazole with nelfinavir is contraindicated, and co-administration with atazanavir is not recommended; if considered unavoidable with atazanavir, close clinical monitoring is required and the atazanavir dose

should be increased, though even an increased dose may not overcome the interaction. Esomeprazole has no clinically relevant effect on exposure of darunavir, amprenavir or lopinavir when combined with ritonavir. It may increase exposure to saquinavir.

Methotrexate

Proton pump inhibitors may increase methotrexate levels. Temporary withdrawal of esomeprazole should be considered during high-dose methotrexate therapy.

Tacrolimus

Esomeprazole may increase serum levels of tacrolimus. Monitoring of tacrolimus concentrations and renal function is recommended, with dose adjustment of tacrolimus if needed.

Medicinal products with pH-dependent absorption

Esomeprazole-induced suppression of gastric acid secretion may decrease or increase the absorption of medicinal products with a gastric pH-dependent absorption mechanism, such as ketoconazole and itraconazole (decreased absorption) and erlotinib (decreased absorption), or digoxin (increased absorption). Patients taking digoxin, particularly the elderly on high doses, should be monitored.

Medicinal products metabolised by CYP2C19

Esomeprazole may increase plasma concentrations of medicinal products metabolised by CYP2C19, such as diazepam, citalopram and phenytoin. Dose reduction of these products may be required, particularly during on-demand use of esomeprazole.

Diazepam

Concomitant administration of esomeprazole reduces the clearance of diazepam, a CYP2C19 substrate, by 45%.

Warfarin

No clinically significant effect on coagulation was seen in clinical trials, but rare cases of clinically significant increases in INR have been reported. Monitoring is recommended when treatment with esomeprazole is started or stopped in patients receiving warfarin or other coumarin derivatives.

Effects of other medicinal products on the pharmacokinetics of esomeprazole

Medicinal products which inhibit CYP2C19 and/or CYP3A4

Esomeprazole is metabolised by CYP2C19 and CYP3A4. Concomitant administration with CYP3A4 and CYP2C19 inhibitors, such as clarithromycin or voriconazole, may lead to increased esomeprazole exposure. Dose adjustment is generally not required, but should be considered in patients with severe hepatic impairment or during long-term treatment.

Medicinal products which induce CYP2C19 and/or CYP3A4

Medicinal products known to induce CYP2C19 or CYP3A4, or both, such as rifampicin and St. John's Wort, may lead to decreased esomeprazole plasma levels.

Paediatric population

Interaction studies have only been performed in adults.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited data on the use of esomeprazole in pregnant women. Esomeprazole should be used during pregnancy only if clearly needed and after careful benefit-risk assessment.

Breast-feeding

It is not known whether esomeprazole is excreted in human breast milk. Esomeprazole should not be used during breast-feeding unless clearly necessary.

Fertility

Animal data on esomeprazole do not indicate effects on fertility.

4.7 Effects on ability to drive and use machines

Esomeprazole may cause adverse reactions such as dizziness and blurred vision. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

The following adverse reactions have been reported with esomeprazole:

- Headache
- Leukopenia
- Thrombocytopenia
- Hypersensitivity reactions (e.g. fever, angioedema and anaphylactic reaction/shock)
- Hyponatraemia
- Agitation, confusion, depression
- Taste disturbance
- Blurred vision
- Abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting
- Hepatitis with or without jaundice
- Malaise, increased sweating

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Experience with deliberate overdosage is limited to date. Symptoms described in connection with a dose of 280 mg included gastrointestinal symptoms and weakness. Single doses of 80 mg esomeprazole were uneventful. No specific antidote for esomeprazole overdose is known. Esomeprazole is extensively plasma protein bound and is therefore not readily dialysable.

Treatment:

As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilised.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Proton Pump Inhibitor.

ATC Code: A02BC05

Mechanism of action

Esomeprazole is a weak base and is concentrated and converted to the active form in the highly acidic environment of the secretory canaliculi of the parietal cell, where it inhibits the enzyme H+K+-ATPase, the acid pump, thereby inhibiting both basal and stimulated gastric acid secretion.

5.2 Pharmacokinetic properties

Absorption

Esomeprazole is acid labile and is administered orally as enteric-coated granules. In vivo conversion to the R-isomer is negligible. Absorption of esomeprazole is rapid, with peak plasma levels occurring approximately 1-2 hours after dosing. The absolute bioavailability is 64% after a single dose of 40 mg and increases to 89% with repeated once-daily administration. For a 20 mg dose of esomeprazole, the corresponding values are 50% and 68% respectively.

Distribution

The apparent volume of distribution at steady state in healthy subjects is approximately 0.22 L/kg body weight. Esomeprazole is 97% bound to plasma proteins.

Biotransformation

Esomeprazole is completely metabolised by the cytochrome P450 (CYP) system. The major part of esomeprazole metabolism is dependent on the polymorphic CYP2C19, responsible for the formation of the hydroxy- and desmethyl metabolites of esomeprazole. The remaining part is dependent on another specific isoform, CYP3A4, responsible for the formation of esomeprazole sulphone, the main metabolite in plasma.

Elimination

Esomeprazole is rapidly cleared from plasma with no accumulation during once-daily use. Esomeprazole is almost completely metabolised, with its major metabolites having no effect on gastric acid secretion. Around 80% of an oral dose is excreted as metabolites in the urine, with the remainder in the faeces, and minimal unchanged drug is excreted in the urine.

5.3 Preclinical safety data

[Preclinical safety data (e.g. carcinogenicity, mutagenicity, reproductive toxicity findings) — not provided in the available source materials; to be confirmed and provided.]

6. Pharmaceutical particulars

6.1 List of excipients

Mannitol
Sodium Carbonate Anhydrous
Microcrystalline Cellulose (M.C.C.P Avicel-102)

Croscarmellose Sodium
Povidone (P.V.P.K-30)
Crospovidone (Crospovidone XL)
Sodium Lauryl Sulfate
Magnesium Stearate
Sodium Starch Glycolate (Type A)
Purified Talc
Colloidal Anhydrous Silica
Aqueous Enteric Coat (DR Coat ECA)
Seal Coat (DR Coat Seal)

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store in a cool and dry place. Protect from light. Do not store above 30°C.

6.5 Nature and contents of container
10 tablets are packed in Alu-Alu blister. Three (3) such blisters are packed in a printed carton along with a packing insert.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing authorisation holder
Modest Healthcare LTD
Nairobi, Kenya.

8. Marketing authorisation number
H2013/CTD582/281/R1

9. Date of first authorisation/renewal of the authorisation
2nd March 2026

10. Date of revision of the text
26th August 2026