Summary of product characteristics (SmPC)

1.Name of the medicinal product
Gastiprazole 40

2.Qualitative and quantitative composition
Each Enteric coated tablet contains:
Esomeprazole Magnesium Trihydrate BP
Eq. to Esomeprazole.....40 mg
For the full list of excipients, see section 6.1.

3.Pharmaceutical form
Yellow colored round shaped Enteric coated tablet having break line on one side and plain on the other side.

4.Clinical particulars
4.1 Therapeutic indications
Esomeprazole Gastro-resistant tablets are indicated in adults for:

Gastroesophageal Reflux Disease (GERD)

- Treatment of erosive reflux esophagitis.

- Long-term management of patients with healed esophagitis to prevent relapse.

- Symptomatic treatment of gastroesophageal reflux disease (GERD).

In combination with appropriate antibacterial therapeutic regimens for the eradication of Helicobacter pylori and

- Healing of Helicobacter pylori associated duodenal ulcer.

- Prevention of relapse of peptic ulcers in patients with Helicobacter pylori associated ulcers.

Patients requiring continued NSAID therapy

- Healing of gastric ulcers associated with NSAID therapy.

- Prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk.

Prolonged treatment after I.V. induced prevention of rebleeding of peptic ulcers

Treatment of Zollinger Ellison Syndrome

Esomeprazole gastro-resistant tablets are indicated in adolescents from the age of 12 years for:

Gastroesophageal Reflux Disease (GERD)

- Treatment of erosive reflux esophagitis.

- Long-term management of patients with healed esophagitis to prevent relapse.

- Symptomatic treatment of gastroesophageal reflux disease (GERD).

In combination with antibiotics in treatment of duodenal ulcer caused by Helicobacter pylori.

4.2 Posology and method of administration Gastroesophageal Reflux Disease (GERD)

Healing of Erosive Esophagitis	**20 mg or 40 mg Once Daily for 4 to 8 Weeks**
Maintenance of Healing of Erosive Esophagitis	20 mg Once Daily
Prevention of relapse of esophagitis	20 mg Once Daily

H. Pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence Triple Therapy:

Esomeprazole	40 mg	Once Daily for 10 days
Amoxicillin	1000 mg	Once Daily for 10 days
Clarithromycin	500 mg	Once Daily for 10 days

4.3 Contraindications

Esomeprazole Gastro resistant Tablets is contraindicated in patients with known hypersensitivity to any component of the formulation or to substituted benzimidazoles.

Esomeprazole should not be used concomitantly with nelfinavir.

4.4 Special warnings and precautions for use

General

Symptomatic response to therapy with Esomeprazole Magnesium does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole, of which Esomeprazole Magnesium is an enantiomer.

Information for Patients

Patients should be informed of the following:

• Esomeprazole Gastro resistant Tablets tablets should be taken at least one hour before meals.

• Antacids may be used while taking Esomeprazole Gastro resistant Tablets.

4.5 Interaction with other medicinal products and other forms of interaction

Esomeprazole is extensively metabolized in the liver by CYP2C19 and CYP3A4.

In vitro and in vivo studies have shown that Esomeprazole is not likely to inhibit CYPs 1A2, 2A6, 2C9, 2D6, 2E1 and 3A4. No clinically relevant interactions with drugs metabolized by these CYP enzymes would be expected. Drug interaction studies have shown that Esomeprazole does not have any clinically significant interactions with phenytoin, warfarin, quinidine, clarithromycin or amoxicillin.

Esomeprazole may potentially interfere with CYP2C19, the major Esomeprazole metabolizing enzyme. Coadministration of Esomeprazole

30mg and diazepam, a CYP2C19 substrate, resulted in a 45% decrease in clearance of diazepam. Increased plasma levels of diazepam were observed 12 hours after dosing and onwards. However, at that time, the plasma levels of diazepam were below the therapeutic interval, and thus this interaction is unlikely to be of clinical relevance. Esomeprazole inhibits gastric acid secretion. Therefore, Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g., ketoconazole, iron salts and digoxin). Coadministration of oral contraceptives, diazepam, phenytoin, or quinidine did not seem to change the pharmacokinetic profile of Esomeprazole.

4.6 Pregnancy and lactation

Pregnancy Category B

Teratology studies performed in rats at oral doses up to 280 mg/kg/day (about 57 times the human dose on a body surface area basis) and in rabbits at oral doses up to 86 mg/kg/day (about 35 times the human dose on a body surface area basis) revealed no evidence of impaired fertility or harm to the foetus due to Esomeprazole. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

The excretion of Esomeprazole in milk has not been studied. Since Esomeprazole is likely to be excreted in human milk, because of the potential for serious adverse reactions in nursing infants from Esomeprazole, 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

Esomeprazole has minor influence on the ability to drive or use machines. Adverse reactions such as dizziness (uncommon) and blurred vision (rare) has been reported . If affected patients should not drive or use machines.

4.8 Undesirable effects

Esomeprazole Magnesium was well tolerated in both short and long-term clinical trials. The most frequently occurring adverse events (≥1%) with Esomeprazole 20 mg and 40mg were headache, diarrhoea, nausea, flatulence, abdominal pain, constipation, and dry mouth.

Summary of the safety profile

Headache, abdominal pain, diarrhoea and nausea are among those adverse reactions that have been most commonly reported in clinical trials (and also from post-marketing use). In addition, the safety profile is similar for different formulations, treatment indications, age groups and patient populations. No dose-related adverse reactions have been identified.

Tabulated list of adverse reactions

The following adverse drug reactions have been identified or suspected in the clinical trials programme for esomeprazole and post-marketing. None was found to be dose-related. The reactions are classified according to frequency: very common (≥ 1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

Blood and lymphatic system disorders

Rare: Leukopenia, thrombocytopenia.

Very rare: Agranulocytosis, pancytopenia.

Immune system disorders

Rare: Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock.

Metabolism and nutrition disorders

Uncommon: Peripheral oedema.

Rare: Hyponatraemia.

Not known: Hypomagnesaemia (see section 4.4); severe hypomagnesaemia can correlate with hypocalcaemia. Hypomagnesaemia may also be associated with hypokalaemia.

Psychiatric disorders

Uncommon: Insomnia.

Rare: Agitation, confusion, depression.

Very rare: Aggression, hallucinations.

Nervous system disorders

Common: Headache.

Uncommon: Dizziness, paraesthesia, somnolence.

Rare: Taste disturbance.

Eye disorders

Rare: Blurred vision.

Ear and labyrinth disorders

Uncommon: Vertigo.

Respiratory, thoracic and mediastinal disorders

Rare: Bronchospasm.

Gastrointestinal disorders

Common: Abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting, fundic gland polyps (benign).

Uncommon: Dry mouth.

Rare: Stomatitis, gastrointestinal candidiasis.

Not known: Microscopic colitis.

Hepatobiliary disorders

Uncommon: Increased liver enzymes.

Rare: Hepatitis with or without jaundice.

Very rare: Hepatic failure, encephalopathy in patients with pre-existing liver disease.

Skin and subcutaneous tissue disorders

Uncommon: Dermatitis, pruritus, rash, urticaria.

Rare: Alopecia, photosensitivity.

Very rare: Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS).

Not known: Subacute cutaneous lupus erythematosus (see section 4.4).

Musculoskeletal and connective tissue disorders

Uncommon: Fracture of the hip, wrist or spine (see section 4.4).

Rare: Arthralgia, myalgia.

Very rare: Muscular weakness.

Renal and urinary disorders

Very rare: Interstitial nephritis; in some patients renal failure has been reported concomitantly.

Reproductive system and breast disorders

Very rare: Gynaecomastia.

General disorders and administration site conditions

Rare: Malaise, increased sweating.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important as it allows continued monitoring of the benefit–risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the marketing authorisation holder or, where applicable, via the national reporting system.

4.9 Overdose
There is very limited experience to date with deliberate overdose. The symptoms described in connection with 280 mg were gastrointestinal symptoms and weakness. Single doses of 80 mg esomeprazole were uneventful. No specific antidote is known. Esomeprazole is extensively plasma protein bound and is therefore not readily dialyzable. 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: A02B C05

Mechanism of Action
Esomeprazole is the S-isomer of omeprazole and reduces gastric acid secretion through a specific targeted 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 and inhibits both basal and stimulated acid secretion.

5.2 Pharmacokinetic properties Absorption
After oral administration of Esomeprazole magnesium, peak plasma levels (Cmax) occur at approximately 1.5 hours (Tmax). The Cmax increases proportionally when the dose is increased and there is a three-fold increase in the area under the plasma concentration-time curve (AUC) from 20 to 40 mg. At repeated once daily dosing with 40 mg, the systemic bioavailability is approximately 90% compared to 64% after a single dose of 40 mg. The mean exposure (AUC) to Esomeprazole increases from 4.32 µmol.hr/L on day 1 to 11.2 µmol.hr/L on day 5 after 40mg once daily dosing. The AUC after administration of a single 40mg dose of Esomeprazole is decreased by 33-53% after food intake compared to fasting conditions. Esomeprazole should be taken at least one hour before meals.

Distribution
Esomeprazole is 97% bound to plasma proteins. Plasma protein binding is constant over the concentration range of 2-20 µmol/L. The apparent volume of distribution at steady state in healthy volunteers is approximately 16 L.

Metabolism
Esomeprazole is extensively metabolized in the liver by the cytochrome P450 (CYP) enzyme system. Following administration of equimolar

doses, the S-and R-isomers are metabolized differently by the liver, resulting in higher plasma levels of the S- than of the R-isomer.

Excretion

The plasma elimination half-life of Esomeprazole is approximately 1-1.5 hours. Less than 1% of parent drug is excreted in the urine. Approximately 80% of an oral dose of Esomeprazole is excreted as inactive metabolites in the urine and the remainder is found as inactive metabolites in the faeces.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development. Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:

Carcinogenicity studies in the rat with the racemic mixture (omeprazole) have shown gastric ECL-cell hyperplasia and carcinoids. These gastric effects in the rat are the result of sustained, pronounced hypergastrinaemia secondary to reduced production of gastric acid and are observed after long-term treatment in the rat with inhibitors of gastric acid secretion.

6.Pharmaceutical particulars

6.1 List of excipients

Esomeprazole Magnesium
Trihydrate Sodium Carbonate
Anhydrous Mannitol (Parlitol
200SD) Crosprovidon XL 10
PVPK 30
Isopropyl Alcohol
Crosprovidon XL 10
Sodium lauryl
Sulphate
Croscarmellose
Sodium Magnesium
Stearate
Color Seal Coat
Transparent Isopropyl
Alcohol Methylene
Dichloride
Color Quinoline Yellow Enteric
Coat Isopropyl Alcohol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in cool & dry place. Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

Aluminium - Aluminium Blister Pack
10 Tablet are blister packed with Aluminium - Aluminium foil; such 3 blisters are packed in one carton pack.
Pack size: 3 x 10 Tablets (i.e. 30 Tablets) in one carton box along with packing leaflet.

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 authorization holder and manufacturing site addresses
Marketing
authorization
Warehouse
pharmaceuticals
P.o Box 1120-00100
GPO, Nairobi
Email: warehousepharmaceuticals@gmail.com
MANUFACTURING SITE
TNS PHARMA PRIVATE LIMITED,
Plot No. 4232, Road No. 42,
Sachin GIDC, Surat –
394230

8. Marketing authorization number
H2026/CTD12958/28310

9.Date of first authorisation/renewal of the authorisation
19th June 2026

10. Date of revision of the text
19th June 2026