SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
Gastiprazole 40 (Esomeprazole Gastro Resistant Tablets BP 40 mg)

Each Enteric coated tablet contains:
Esomeprazole Magnesium Trihydrate BP
Eq. to Esomeprazole.....40 mg
Excipients..... Q.S
Color: Yellow Oxide of Iron

2. Qualitative and quantitative composition
Each Tablet contains 40 mg of Esomeprazole Magnesium Trihydrate BP Eq. to Esomeprazole 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
Treatment of Gastroesophageal Reflux Disease (GERD) Healing of Erosive Esophagitis Esomeprazole Gastro Resistant Tablets is indicated for the short-term treatment (4 to 8 weeks) in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis. For those patients who have not healed after 4-8 weeks of treatment, an additional 4-8-week course of Esomeprazole Gastro resistant Tablets 40 mg may be considered.

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.

SUMMARY OF PRODUCT CHARACTERISTICS

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, decision should be made whether to discontinue nursing or the discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines
None

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.

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

4.9 Overdose
There have been no reports of overdose with Esomeprazole. Reports have been received of over dosage with omeprazole in humans. Doses ranged up to 2,400 mg (120 times the usual recommended clinical dose). Manifestations were variable, but included confusion, drowsiness, blurred vision, tachycardia, nausea, diaphoresis, flushing, headache, dry mouth, and other adverse reactions similar to those seen in normal clinical experience. No specific antidote for Esomeprazole is known. Since Esomeprazole is extensively protein bound, it is not expected to be removed by dialysis. In the event of over dosage, treatment should be symptomatic and supportive.

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

-Not applicable.

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.

SUMMARY OF PRODUCT CHARACTERISTICS

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

CTD12958

9. Date of first registration

05/05/2026

10. DATE OF REVISION OF THE TEXT

05/05/2026