Summary of Product Characteristics
SHALCER 40
(Esomeprazole Gastro-resistant Tablets 40 mg)

---

1. Name of the medicinal product

SHALCER 40

Esomeprazole Gastro-resistant Tablets 40 mg

2. Qualitative and quantitative composition

Each gastro-resistant tablet contains esomeprazole magnesium trihydrate USP equivalent to 40 mg of esomeprazole.

Excipients with known effect
Each gastro-resistant tablet contains mannitol and the preservatives methyl parahydroxybenzoate and propyl parahydroxybenzoate. It contains less than 1 mmol (23 mg) of sodium per tablet.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Gastro-resistant tablet (enteric-coated tablet).

Pink, caplet-shaped, enteric-coated tablets.

4. Clinical particulars

4.1 Therapeutic indications

SHALCER 40 is indicated in:

Adults

Gastro-oesophageal reflux disease (GERD)

- treatment of erosive reflux oesophagitis;
- long-term management of patients with healed oesophagitis to prevent relapse;
- symptomatic treatment of gastro-oesophageal reflux disease (GERD).

In combination with appropriate antibacterial therapy for the eradication of Helicobacter pylori

- 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.

Other

- treatment of Zollinger-Ellison syndrome.

Adolescents from the age of 12 years

- Gastro-oesophageal reflux disease (GERD): treatment of erosive reflux oesophagitis; long-term management of healed oesophagitis to prevent relapse; and symptomatic treatment of GERD.
- In combination with antibiotics, treatment of duodenal ulcer caused by Helicobacter pylori.

4.2 Posology and method of administration

Posology – Adults

Gastro-oesophageal reflux disease (GERD)

Treatment of erosive reflux oesophagitis: 40 mg once daily for 4 weeks. An additional 4 weeks of treatment is recommended for patients in whom oesophagitis has not healed or who have persistent symptoms. Long-term management of healed oesophagitis to prevent relapse: 20 mg once daily. Symptomatic treatment of GERD: 20 mg once daily in patients without oesophagitis; if symptom control is not achieved after 4 weeks, the patient should be further investigated. Once symptoms have resolved, control may be maintained with 20 mg once daily, including an on-demand regimen of 20 mg once daily when needed. An on-demand regimen is not recommended in NSAID-treated patients at risk of gastric and duodenal ulcers.

Eradication of Helicobacter pylori

20 mg esomeprazole with 1 g amoxicillin and 500 mg clarithromycin, all twice daily for 7 days, for the healing of H. pylori-associated duodenal ulcer and prevention of relapse of peptic ulcers in H. pylori-associated ulcers.

Patients requiring continued NSAID therapy

Healing of NSAID-associated gastric ulcers: 20 mg once daily for 4 to 8 weeks. Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk: 20 mg once daily.

Prolonged treatment after intravenous-induced prevention of rebleeding of peptic ulcers

40 mg once daily for 4 weeks after intravenous-induced prevention of rebleeding of peptic ulcers.

Zollinger-Ellison syndrome

The recommended initial dose is 40 mg twice daily, then individually adjusted and continued as long as clinically indicated. Most patients can be controlled on 80 to 160 mg daily; doses above 80 mg daily should be divided and given twice daily.

Paediatric population – Adolescents from the age of 12 years

Gastro-oesophageal reflux disease: treatment of erosive reflux oesophagitis, 40 mg once daily for 4 weeks (with an additional 4 weeks if not healed or symptoms

persist); long-term management of healed oesophagitis, 20 mg once daily; symptomatic GERD, 20 mg once daily. Treatment of H. pylori-associated duodenal ulcer should be supervised by a specialist, with consideration of official guidance on bacterial resistance and appropriate antibacterial use; the recommended regimen is:

Body weight	**Posology**
30 – 40 kg	In combination with two antibiotics: esomeprazole 20 mg, amoxicillin 750 mg and clarithromycin 7.5 mg/kg body weight, all administered together twice daily for one week.
> 40 kg	In combination with two antibiotics: esomeprazole 20 mg, amoxicillin 1 g and clarithromycin 500 mg, all administered together twice daily for one week.

Children below the age of 12 years
This medicinal product should not be used in children younger than 12 years, as no data are available; more appropriate pharmaceutical forms of esomeprazole may be available.

Special populations

Renal impairment
No dose adjustment is required. Owing to limited experience in severe renal insufficiency, such patients should be treated with caution (see section 5.2).

Hepatic impairment
No dose adjustment is required in mild to moderate hepatic impairment. In severe hepatic impairment, a maximum dose of 20 mg should not be exceeded.

Elderly
No dose adjustment is required in the elderly.

Method of administration
The tablets should be swallowed whole with liquid and should not be chewed or crushed. For patients with difficulty swallowing, the tablets may be dispersed in half a glass of non-carbonated water (no other liquid 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, then rinse the glass with half a glass of water and drink. For patients who cannot swallow, the tablets may be dispersed in non-carbonated water and administered through a gastric tube, ensuring the suitability of the selected syringe and tube. The pellets must not be chewed or crushed.

4.3 Contraindications

- Hypersensitivity to the active substance, to substituted benzimidazoles, or to any of the excipients listed in section 6.1.
- Esomeprazole must not be used concomitantly with nelfinavir (see section 4.5).

4.4 Special warnings and precautions for use

Serious conditions and alarm symptoms

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

Long-term use and on-demand treatment

Patients on long-term treatment (particularly for more than a year) should be kept under regular surveillance. Patients on on-demand treatment should be instructed to contact their physician if their symptoms change in character.

Helicobacter pylori eradication

When esomeprazole is used for H. pylori eradication, possible drug interactions for all components of the triple therapy should be considered. Clarithromycin is a potent CYP3A4 inhibitor, so its contraindications and interactions should be considered when the triple therapy is used in patients concurrently taking other CYP3A4-metabolised medicinal products.

Gastrointestinal infections

Treatment with proton pump inhibitors may slightly increase the risk of gastrointestinal infections such as Salmonella and Campylobacter.

Absorption of vitamin B12

Esomeprazole, like all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) owing to hypo- or achlorhydria; this should be considered in patients with reduced body stores or risk factors for reduced vitamin B12 absorption on long-term therapy.

Hypomagnesaemia

Severe hypomagnesaemia has been reported in patients treated with PPIs for at least three months, in most cases for a year. Serious manifestations (fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia) may begin insidiously and be overlooked. In most patients, hypomagnesaemia improved after magnesium replacement and discontinuation of the PPI. In patients expected to be on prolonged treatment, or taking PPIs with digoxin or medicinal products that may cause hypomagnesaemia (e.g. diuretics), magnesium levels should be considered before and periodically during treatment.

Risk of fracture

Proton pump inhibitors, especially at high doses and over long durations (> 1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in the presence of other recognised risk factors. Patients at risk of osteoporosis should be managed according to current clinical guidelines and have an adequate intake of vitamin D and calcium.

Subacute cutaneous lupus erythematosus (SCLE)

Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of skin, and are accompanied by

arthralgia, the patient should seek medical help promptly and discontinuation of esomeprazole should be considered. SCLE after previous PPI treatment may increase the risk of SCLE with other PPIs.

Combination with other medicinal products

Co-administration with atazanavir is not recommended (see section 4.5). Esomeprazole is a CYP2C19 inhibitor; the potential for interactions with CYP2C19-metabolised medicinal products should be considered when starting or stopping treatment. As a precaution, concomitant use with clopidogrel should be discouraged.

Interference with laboratory tests

Increased chromogranin A (CgA) levels may interfere with investigations for neuroendocrine tumours. To avoid this, esomeprazole should be stopped for at least 5 days before CgA measurement; if CgA and gastrin levels have not returned to the reference range, the measurement should be repeated 14 days after cessation.

Excipients

This medicinal product contains mannitol, which may have a mild laxative effect. It also contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed). It contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Effects of esomeprazole on other medicinal products

- Medicinal products with pH-dependent absorption: acid suppression may alter absorption; the absorption of ketoconazole, itraconazole and erlotinib may decrease and that of digoxin may increase. Caution is advised with high-dose esomeprazole in elderly patients, and digoxin monitoring should be reinforced.
- Antiretrovirals: for atazanavir and nelfinavir, decreased serum levels have been reported; concomitant use with nelfinavir is contraindicated and with atazanavir is not recommended. For saquinavir, increased serum levels have been reported. The mechanism may involve increased gastric pH and CYP2C19 inhibition.
- Methotrexate: levels may increase with PPIs; a temporary withdrawal of esomeprazole may be considered with high-dose methotrexate.
- Tacrolimus: serum levels may increase; monitor tacrolimus concentrations and renal function and adjust the dose if needed.
- CYP2C19 substrates (e.g. diazepam, citalopram, imipramine, clomipramine, phenytoin): plasma concentrations may increase and a dose reduction may be needed. Esomeprazole 30 mg reduced diazepam clearance by 45%; monitoring of phenytoin is recommended when esomeprazole is introduced or withdrawn.

- Warfarin and other coumarin derivatives: isolated cases of clinically significant elevated INR have been reported; monitoring is recommended when starting and stopping esomeprazole.
- Cilostazol and cisapride: exposure may be increased through CYP2C19 inhibition.
- Clopidogrel: exposure to the active metabolite is decreased by about 40%, with a small reduction in platelet inhibition; concomitant use should be discouraged.
- No clinically relevant interaction was seen with amoxicillin, quinidine, naproxen or rofecoxib.

Effects of other medicinal products on esomeprazole

Esomeprazole is metabolised by CYP2C19 and CYP3A4. CYP3A4 inhibitors (e.g. clarithromycin) and combined CYP2C19/CYP3A4 inhibitors (e.g. voriconazole) may substantially increase esomeprazole exposure; dose adjustment is not routinely required but should be considered in severe hepatic impairment and long-term treatment. Inducers of CYP2C19 or CYP3A4 (e.g. rifampicin, St John's wort) may decrease esomeprazole serum levels.

4.6 Fertility, pregnancy and lactation

Pregnancy

A moderate amount of data on pregnant women (between 300 and 1,000 pregnancy outcomes) indicates no malformative or foeto/neonatal toxicity of esomeprazole. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Caution should nevertheless be exercised when prescribing to pregnant women.

Breast-feeding

It is not known whether esomeprazole is excreted in human breast milk, and there is insufficient information on its effects in newborns/infants. Esomeprazole should not be used during breast-feeding.

Fertility

Animal studies with the racemic mixture omeprazole given orally do not indicate effects on fertility.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Summary of the safety profile

Headache, abdominal pain, diarrhoea and nausea are among the most commonly reported adverse reactions in clinical trials and from post-marketing use. The safety profile is similar across formulations, indications, age groups and patient populations, and no dose-related adverse reactions have been identified.

Tabulated list of adverse reactions

Frequency categories are defined as: 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); and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Undesirable effect
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 and 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)
	Not known	Subacute cutaneous lupus erythematosus

System Organ Class	Frequency	Undesirable effect
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 (renal failure has been reported concomitantly in some patients)
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. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the National Regulatory Authority.

4.9 Overdose

Symptoms

Experience of deliberate overdose is very limited. Symptoms described in connection with 280 mg were gastrointestinal disturbances and weakness; single doses of 80 mg were uneventful.

Management

No specific antidote is known. Esomeprazole is extensively plasma protein bound and is therefore not readily dialysable. As in any case of overdose, treatment should be symptomatic, with general supportive measures.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: drugs for acid-related disorders, proton pump inhibitors. ATC code: A02BC05.

Mechanism of action

Esomeprazole is the S-isomer of omeprazole and reduces gastric acid secretion through a specifically targeted mechanism of action. It is a weak base that 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), inhibiting both basal and stimulated acid secretion.

Pharmacodynamic effects

After oral dosing with 20 mg or 40 mg, the onset of effect occurs within one hour. After five days of dosing, the mean time for which intragastric pH was above 4 over 24 hours was 13 hours with 20 mg and 17 hours with 40 mg. Healing of reflux oesophagitis with 40 mg occurs in about 78% of patients after four weeks

and 93% after eight weeks, and one week of triple therapy achieves H. pylori eradication in about 90% of patients. During antisecretory treatment, serum gastrin and chromogranin A increase in response to decreased acid secretion, the latter potentially interfering with investigations for neuroendocrine tumours.

5.2 Pharmacokinetic properties

Absorption

Esomeprazole is acid-labile and is administered orally as gastro-resistant granules. Absorption is rapid, with peak plasma levels approximately 1 to 2 hours after dosing. The absolute bioavailability is 64% after a single 40 mg dose, increasing to 89% after repeated once-daily administration. Food both delays and decreases absorption, without a significant influence on the effect on intragastric acidity.

Distribution

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

Biotransformation

Esomeprazole is completely metabolised by the cytochrome P450 system, mainly by the polymorphic CYP2C19 (forming the hydroxy and desmethyl metabolites), with the remainder by CYP3A4 (forming the sulphone metabolite).

Elimination

Total plasma clearance is about 17 L/h after a single dose and about 9 L/h after repeated administration, with a plasma elimination half-life of about 1.3 hours after repeated once-daily dosing. Almost 80% of an oral dose is excreted as metabolites in the urine and the remainder in the faeces, with less than 1% of parent drug in the urine.

Special populations

About 2.9% of the population lack a functional CYP2C19 enzyme (poor metabolisers), in whom esomeprazole AUC is roughly doubled; this has no implications for posology. Exposure is somewhat higher in women and in severe hepatic impairment (where a maximum of 20 mg should not be exceeded). Pharmacokinetics are not significantly changed in renal impairment or in the elderly, and in adolescents aged 12 to 18 years exposure is similar to that in adults.

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 and reproductive and developmental toxicity. Carcinogenicity studies in the rat with the racemic mixture have shown gastric ECL-cell hyperplasia and carcinoids, which are the result of sustained, pronounced hypergastrinaemia secondary to reduced gastric acid production and are observed after long-term treatment with inhibitors of gastric acid secretion. No new or unexpected toxicity

findings were observed in juvenile rats and dogs after administration of esomeprazole for up to 3 months compared with adult animals.

6. Pharmaceutical particulars

6.1 List of excipients

- Light magnesium oxide
- Mannitol
- Povidone (K-30)
- Methyl parahydroxybenzoate
- Propyl parahydroxybenzoate
- Acetone
- Maize starch
- Microcrystalline cellulose
- Magnesium stearate
- Purified talc
- Sodium starch glycolate
- Colloidal anhydrous silica
- Titanium dioxide
- Red iron oxide
- Isopropyl alcohol
- Dichloromethane
- Seal coat (SC4S)
- Enteric coat (EC4S)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30°C. Keep out of the reach of children.

6.5 Nature and contents of container

10 tablets in an Alu blister; three blisters (30 tablets) packed in one mono carton together with a package insert.

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

SHALINA HEALTHCARE KENYA LIMITED

Mombasa/Block XXX/178, Nkurumah Road, P.O. Box 80436-80100, Mombasa, Kenya.

Manufacturer
ZAIN PHARMA LIMITED

Plot No. 209/13741, Colchester Park, Go-Down No. 1, 2, 3, Off Mombasa Road, P.O. Box 100167-00101, Nairobi, Kenya.

8. Marketing Authorisation Number

CTD10258

9. Date of first authorisation / renewal of the authorisation

03.07.2026

10. Date of revision of the text

02.07.2026