SUMMARY OF PRODUCT CHARACTERISTICS
SHALCER 20 (Esomeprazole Tablets 20 mg)

1. NAME OF THE MEDICINAL PRODUCT

SHALCER 20 (Esomeprazole Magnesium Trihydrate Enteric-Coated Tablets 20 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each enteric-coated tablet contains 20 mg esomeprazole (as esomeprazole magnesium trihydrate USP).

Excipients with known effect:

This medicinal product contains sucrose and lactose monohydrate. For warnings, see section 4.4.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Enteric-coated tablet.

Pink, round, biconcave, enteric-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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 GERD.

In combination with appropriate antibacterial therapeutic regimens for the eradication of Helicobacter pylori and healing of H. pylori-associated duodenal ulcer; prevention of relapse of peptic ulcers in patients with H. 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.

Treatment of Zollinger-Ellison syndrome.

Adolescents from the age of 12 years

GERD: treatment of erosive reflux oesophagitis; long-term management of patients with healed oesophagitis to prevent relapse; symptomatic treatment of GERD. In combination with antibiotics for the treatment of duodenal ulcer caused by H. pylori.

4.2 Posology and method of administration

Adults

Erosive reflux oesophagitis: 20 mg once daily for 4 weeks. An additional 4 weeks treatment is recommended for patients in whom oesophagitis has not healed or who have persistent symptoms.

Maintenance of healed oesophagitis: 20 mg once daily.

Symptomatic GERD without oesophagitis: 20 mg once daily. If symptom control has not been achieved after 4 weeks, the patient should be further investigated.

H. pylori eradication: 20 mg esomeprazole with 1 g amoxicillin and 500 mg clarithromycin, all twice daily for 7 days.

Healing of NSAID-associated gastric ulcers: 20 mg once daily for 4–8 weeks.

Prevention of NSAID-associated gastric and duodenal ulcers: 20 mg once daily.

Zollinger-Ellison syndrome: recommended initial dose 40 mg twice daily, adjusted individually; most patients can be controlled on doses of 80–160 mg daily.

Adolescents from 12 years

GERD (erosive oesophagitis, maintenance, symptomatic): 20 mg once daily as above.

H. pylori eradication (adolescents, weight 30–40 kg): esomeprazole 20 mg + amoxicillin 750 mg + clarithromycin 7.5 mg/kg twice daily × 1 week; weight >40 kg: esomeprazole 20 mg + amoxicillin 1 g + clarithromycin 500 mg twice daily × 1 week.

SHALCER 20 should not be used in children younger than 12 years.

Special populations

Renal impairment: No dose adjustment required. Caution in patients with severe renal insufficiency due to limited experience.

Hepatic impairment: No dose adjustment required in mild to moderate hepatic impairment. For patients with severe hepatic impairment, a maximum dose of 20 mg should not be exceeded.

Elderly: No dose adjustment required.

Method of administration

Oral. Tablets should be swallowed whole — do not chew. Food intake delays and decreases absorption but does not significantly affect the effect of esomeprazole on intragastric acidity.

4.3 Contraindications

- Hypersensitivity to the active substance, to substituted benzimidazoles or to any of the excipients listed in section 6.1.
- Concomitant use with nelfinavir.

4.4 Special warnings and precautions for use

Malignancy

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

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

H. pylori eradication

When prescribing esomeprazole for H. pylori eradication, possible drug interactions for all components in the triple therapy should be considered. Clarithromycin is a potent inhibitor of CYP3A4; its contraindications and interactions should be considered for patients taking other medicinal products metabolised via CYP3A4 (e.g. cisapride).

Gastrointestinal infections

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

Hypomagnesaemia

Severe hypomagnesaemia has been reported in patients treated with PPIs for at least three months, and in most cases for a year. Serious manifestations include fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia. For patients expected to be on prolonged treatment or who take PPIs with digoxin or medicinal products that may cause hypomagnesaemia (e.g. diuretics), magnesium levels should be considered for measurement before starting PPI treatment and periodically during treatment.

Risk of fracture

Proton pump inhibitors, especially if used in 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 presence of other recognised risk factors. Patients at risk of osteoporosis should receive care according to current clinical guidelines and have adequate intake of vitamin D and calcium.

Subacute cutaneous lupus erythematosus (SCLE)

PPIs are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin and if accompanied by arthralgia, the patient should seek medical help and esomeprazole should be considered for discontinuation. SCLE after previous PPI treatment may increase the risk with other PPIs.

Clopidogrel interaction

Esomeprazole is a CYP2C19 inhibitor. An interaction with clopidogrel resulting in decreased exposure to the active metabolite of clopidogrel has been observed. As a precaution, concomitant use of esomeprazole and clopidogrel should be discouraged.

Atazanavir interaction

Co-administration of esomeprazole with atazanavir is not recommended. If the combination is judged unavoidable, close clinical monitoring is recommended with an increase in the atazanavir dose to 400 mg with 100 mg ritonavir; esomeprazole 20 mg should not be exceeded.

Laboratory test interference

Increased chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, esomeprazole treatment should be stopped for at least 5 days before CgA measurements.

Sucrose and lactose content

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Effect of esomeprazole on the pharmacokinetics of other medicinal products

Medicinal products with pH-dependent absorption:

Gastric acid suppression may decrease or increase the absorption of medicinal products with pH-dependent absorption. Absorption of ketoconazole, itraconazole and erlotinib can decrease and absorption of digoxin can increase. Digoxin toxicity has been rarely reported; therapeutic drug monitoring should be reinforced when esomeprazole is given at high doses to elderly patients.

Nelfinavir and atazanavir:

Concomitant use with nelfinavir is contraindicated. Co-administration with atazanavir is not recommended (see section 4.4).

Methotrexate:

Methotrexate levels may increase in some patients given together with PPIs. In high-dose methotrexate administration, temporary withdrawal of esomeprazole may need to be considered.

CYP2C19 substrates (diazepam, citalopram, imipramine, clomipramine, phenytoin, voriconazole, cilostazol, clopidogrel):

Esomeprazole inhibits CYP2C19. Plasma concentrations of CYP2C19 substrates may be increased; a dose reduction may be needed. Phenytoin plasma levels increase by approximately 13% — monitor when esomeprazole is introduced or withdrawn. For clopidogrel, concomitant use should be discouraged (see section 4.4).

Warfarin:

A few isolated cases of elevated INR of clinical significance have been reported. INR monitoring is recommended when initiating and ending esomeprazole treatment during warfarin therapy.

Tacrolimus:

Concomitant esomeprazole has been reported to increase serum levels of tacrolimus. Reinforced monitoring of tacrolimus concentrations and renal function is recommended.

Effect of other medicinal products on the pharmacokinetics of esomeprazole

CYP2C19 and/or CYP3A4 inhibitors (clarithromycin, voriconazole):

Can increase esomeprazole AUC. Dose adjustment is not regularly required; however, dose adjustment should be considered in patients with severe hepatic impairment on long-term treatment.

CYP2C19 and/or CYP3A4 inducers (rifampicin, St. John's Wort):

May lead to decreased esomeprazole serum levels.

4.6 Fertility, pregnancy and lactation

Pregnancy

A moderate amount of data on pregnant women (between 300–1,000 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 be exercised when prescribing to pregnant women.

Breast-feeding

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

Fertility

Animal studies with the racemic mixture omeprazole given by oral administration do not indicate effects on fertility.

4.7 Effects on ability to drive and use machines

Esomeprazole has 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 post-marketing use. The safety profile is similar for different formulations, treatment indications, age groups and patient populations. No dose-related adverse reactions have been identified.

System Organ Class	Frequency	Adverse Effect
Blood and lymphatic disorders	Rare / Very rare	Leukopenia, thrombocytopenia (rare); agranulocytosis, pancytopenia (very rare)
Immune disorders	Rare	Hypersensitivity reactions e.g. fever, angioedema, anaphylactic reaction/shock
Metabolism and nutrition	Uncommon / Rare / Not known	Peripheral oedema (uncommon); hyponatraemia (rare); hypomagnesaemia (not known)
Psychiatric disorders	Uncommon / Rare / Very rare	Insomnia (uncommon); agitation, confusion, depression (rare); aggression, hallucinations (very rare)
Nervous system disorders	Common / Uncommon / Rare	Headache (common); dizziness, paraesthesia, somnolence (uncommon); taste disturbance (rare)
Eye disorders	Rare	Blurred vision
Ear and labyrinth disorders	Uncommon	Vertigo
Respiratory disorders	Rare	Bronchospasm
Gastrointestinal disorders	Common / Uncommon / Rare / Not known	Abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting, fundic gland polyps (common); dry mouth (uncommon); stomatitis, GI candidiasis (rare); microscopic colitis (not known)
Hepatobiliary disorders	Uncommon / Rare / Very rare	Increased liver enzymes (uncommon); hepatitis with or without jaundice (rare); hepatic failure, encephalopathy in patients with pre-existing liver disease (very rare)
Skin and subcutaneous tissue disorders	Uncommon / Rare / Very rare / Not known	Dermatitis, pruritus, rash, urticaria (uncommon); alopecia, photosensitivity (rare); erythema multiforme, SJS, TEN (very rare); SCLE (not known)
Musculoskeletal disorders	Uncommon / Rare / Very rare	Fracture of hip, wrist or spine (uncommon); arthralgia, myalgia (rare); muscular weakness (very rare)
Renal and urinary disorders	Very rare	Interstitial nephritis; renal failure in some patients concomitantly
Reproductive disorders	Very rare	Gynaecomastia

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 Regulatory Authority.

4.9 Overdose

Symptoms described after 280 mg included gastrointestinal symptoms and weakness. Single doses of 80 mg were uneventful. No specific antidote is known. Esomeprazole is extensively plasma protein bound and is therefore not readily dialyzable. Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Esomeprazole is the S-isomer of omeprazole and reduces gastric acid secretion through a specific targeted mechanism of action. It is a specific inhibitor of the acid pump (H+K+-ATPase) in the parietal cell. After repeated administration with 20 mg esomeprazole once daily for five days, mean peak acid output after pentagastrin stimulation is decreased by 90% when measured 6–7 hours after dosing on day 5.

Healing of reflux oesophagitis with esomeprazole 20 mg occurs in approximately 78% of patients after four weeks, and in 93% after eight weeks. One week's treatment with esomeprazole 20 mg b.i.d. and appropriate antibiotics results in successful H. pylori eradication in approximately 90% of patients.

5.2 Pharmacokinetic properties

Absorption

Rapid absorption; peak plasma levels approximately 1–2 hours after dose. Absolute bioavailability 64% after a single dose of 20 mg and increases to 89% after repeated once-daily administration. Food intake delays and decreases absorption without significant influence on the effect on intragastric acidity.

Distribution

Apparent volume of distribution approximately 0.22 l/kg. Esomeprazole is 97% plasma protein bound.

Biotransformation

Completely metabolised by CYP. The major part is dependent on polymorphic CYP2C19 (hydroxy- and desmethyl metabolites); the remaining part is dependent on CYP3A4 (esomeprazole sulphone).

Elimination

Total plasma clearance approximately 17 l/h after single dose and approximately 9 l/h after repeated administration. Plasma elimination half-life approximately 1.3 hours after repeated once-daily dosing. Approximately 80% of an oral dose is excreted as metabolites in urine, the remainder in faeces. Less than 1% of the parent drug is found in urine.

Poor metabolisers (CYP2C19)

Approximately 2.9% of the population lack a functional CYP2C19 enzyme. In these individuals, mean AUC was approximately 100% higher and Cmax approximately 60% higher than in extensive metabolisers. These findings have no implications for the posology of esomeprazole.

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. Carcinogenicity studies in the rat with the racemic mixture showed gastric ECL-cell hyperplasia and carcinoids; these are a result of sustained, pronounced hypergastrinaemia secondary to reduced gastric acid production and are observed after long-term treatment with inhibitors of gastric acid secretion.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

No.	Excipient
1	Light magnesium oxide
2	Mannitol
3	Polyvinylpyrrolidone K-30
4	Methyl hydroxybenzoate
5	Propyl hydroxybenzoate
6	Acetone
7	Maize starch
8	Microcrystalline cellulose
9	Magnesium stearate
10	Purified talc

No.	Excipient
11	Sodium starch glycolate
12	Colloidal anhydrous silica
13	Titanium dioxide (E171)
14	Iron oxide red (E172)
15	Isopropyl alcohol
16	Dichloromethane
17	Sealcoat SC4S
18	Enteric coat EC4S
19	Sucrose (excipient with known effect)
20	Lactose monohydrate (excipient with known effect)

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store at a temperature not exceeding 30°C. Protect from light. Keep out of the reach and sight of children.

6.5 Nature and contents of container
10 tablets packed in one ALU blister; 3 such blisters packed in one mono carton with package insert. Pack size: 30 tablets.

6.6 Special precautions for disposal and other handling
No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
ZAIN PHARMA LTD.
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Go-Down No. 1, 2, 3, Off Mombasa Road,
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P.O. Box: 100167-00101, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)
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