SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF DRUG PRODUCT

Getzome Capsules 20mg

Strength: 20mg
Pharmaceutical/Dosage Form: Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
Enteric coated pellets of omeprazole equivalent to omeprazole USP....20 mg

3. PHARMACEUTICAL FORM

Hard gelatin capsule with Green opaque cap and white opaque body, printed GETZ logo and RSK-20 containing white to off-white pellets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Getzome (Omeprazole) is indicated for the treatment of:

1. Gastro-Esophageal 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).
2. Gastric and duodenal ulcer.
3. Treatment and prophylaxis of NSAID-associated ulceration.
4. Eradication of *Helicobacter* pylori infection associated with peptic ulcer disease.
5. Zollinger-Ellison syndrome.
6. Dyspepsia.
7. Prophylaxis of acid aspiration.

4.2 Posology/Dosage and method of administration

Getzome (Omeprazole) capsule is given by mouth, which should be swallowed whole and not crushed or chewed.

Symptomatic gastro-esophageal reflux disease (GERD) without esophagitis:
The recommended adult oral dose is 20 mg daily for up to 4 weeks.

Erosive esophagitis:
The recommended adult oral dose for the treatment of patients with erosive esophagitis and accompanying symptoms due to GERD is 20 mg daily for 4 to 8 weeks.

Maintenance of healing of erosive esophagitis:
The recommended adult oral dose is 20 mg daily.

Dosage for children in GERD:
In children, doses in the ranges 0.7 to 1.4 mg per kg body weight daily, up to a maximum daily dose of 40mg have been given for 4 to 12 weeks.

Gastric and duodenal ulcer:
A single daily dose of 20 mg by mouth or 40mg in severe cases is given. Treatment is continued for 4 weeks for duodenal ulcer and 8 weeks for gastric ulcer. Where appropriate, a dose of 10 to 20 mg once daily may be given for maintenance.

NSAID-associated ulceration:
Doses of 20 mg daily are used in the treatment of NSAID-associated ulceration. A dose of 20 mg daily may also be used for prophylaxis in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment.

Helicobacter pylori eradication:
For the eradication of *H.* pylori in peptic ulceration omeprazole 40 mg daily may be combined with antibacterial in dual therapy or omeprazole 20 mg twice daily may be combined with antibacterial in triple therapy. Omeprazole alone may be continued for a further 2 to 8 weeks.

Zollinger-Ellison syndrome:
The initial recommended dosage is 60 mg by mouth once daily, adjusted as required. The majority of patients are effectively controlled by doses in the range 20 to 120 mg daily, but doses up to 120 mg three times daily have been used. Daily doses above 80 mg should be administered in divided doses.

Dyspepsia:
For the relief of acid-related dyspepsia omeprazole is given in usual doses of 10 or 20 mg daily by mouth for 2 to 4 weeks.

Prophylaxis of acid aspiration:
Omeprazole is also used for the prophylaxis of acid aspiration during general anesthesia, in a dose of 40 mg the evening before surgery and a further 40 mg two to six hours before the procedure.

Special Population:

Dosage for Hepatic Impaired Patients:
A maximum daily dose of 20 mg is recommended for patients with impaired hepatic function.

Method of Administration:
Getzome (Omeprazole) capsule is given by mouth, which should be swallowed whole and not crushed or chewed

4.3 Contraindications

Omeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation or to substituted benzimidazoles.

4.4 Special warnings and special precautions for use

General:

- When gastric ulcer is suspected, the possibility of malignancy should be excluded as treatment may alleviate symptoms and delay diagnosis.
- Prior to initiation of dual or triple therapy, the physician should consider the patient with known hypersensitivity reactions to penicillin, macrolides and other antibiotics.

Hepatic impairment:
Consideration should be given to reducing the dose of omeprazole in patients with impaired hepatic function as bioavailability and half-life can increase.

4.5 Interaction with other medicaments

In common with the use of other inhibitors of acid secretion or antacids, the absorption of ketoconazole and itraconazole can decrease during treatment with omeprazole due to decreased intragastric acidity during treatment with omeprazole. Omeprazole is metabolized by CYP2C19. Thus, when omeprazole is combined with drugs metabolised by CYP2C19, such as diazepam, citalopram, imipramine, clomipramine, phenytoin etc., the plasma concentrations of these drugs may be increased and a dose reduction could be needed.

4.6 Fertility, Pregnancy and Lactation

There are no adequate or well-controlled studies in pregnant women. Omeprazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:
It is not known whether omeprazole is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from omeprazole, 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 machine

No effects have been observed.

4.8 Undesirable effects

Omeprazole is well tolerated and the adverse reactions have generally been mild and reversible.

Common
Central and peripheral nervous system: Headache.
Gastrointestinal: Diarrhoea, constipation, abdominal pain, nausea/vomiting and flatulence.

Uncommon
Central and peripheral nervous system: Dizziness, Paraesthesia, somnolence, insomnia and vertigo.
Hepatic: Increased liver enzymes
Skin: Rash and/or pruritis, urticaria
Other: Malaise

Rare
Central and peripheral nervous system: Reversible mental confusion, agitation, aggression, depression and hallucinations, predominantly in severely ill patients.
Endocrine: Gynaecomastia
Gastrointestinal: Dry mouth, stomatitis and gastrointestinal candidiasis.
Haematological: Leukopenia, thrombocytopenia, agranulocytosis and pancytopenia.
Gastro-duodenal carcinoids have been reported in patients with Zollinger-Ellison syndrome on long-term treatment with omeprazole.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Omeprazole reduces gastric acid secretion through a unique mechanism of action. Omeprazole belongs to a new class of anti-secretory compounds, the substituted benzimidazoles that do not exhibit anti-cholinergic or histamine antagonistic properties. It inhibits secretion of gastric acid by
irreversibly blocking the enzyme system of hydrogen/potassium adenosine triphosphatase (H+/K+ ATPase), the proton pump of the gastric parietal cell. This effect is dose-related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus.

5.2 Pharmacokinetic properties

Absorption/Distribution
Omeprazole is acid-labile and is administered orally as enteric-coated pellets in capsules. Omeprazole is rapidly but variably absorbed following oral administration, with peak plasma levels of omeprazole occurring within 0.5 to 3.5 hours. Absorption of omeprazole is not affected by food and also appears to be dose dependant. Increasing the dosage above 40mg has been reported to increase plasma concentrations in a nonlinear fashion because of saturable first pass metabolism. Absorption is higher after long-term administration. The systemic bioavailability of omeprazole is approximately 35%. After repeated once daily administration, the bioavailability increases to about 60%.The plasma protein binding is approximately 95%.

Metabolism & Excretion
Following absorption, omeprazole is almost completely metabolized in the liver, primarily by the cytochrome P450 isoenzyme CYP2C19 to form hydroxy-omeprazole and to a small extent by CYP3A to form omeprazole sulfone. These metabolities are inactive and excreted mostly in the urine and to a lesser extent in the bile. The majority of the dose (about 77%)
is eliminated in the urine and the remainder, recoverable in the feces. The elimination half-life from plasma is reported to be about 0.5 to 3 hours.

Special Population
Pediatric
Available data from children (1 year and older) suggest that the pharmacokinetics within the recommended doses are similar to those reported in adults. At steady state, lower plasma levels of omeprazole were seen in some children.

Geriatric
The bioavailability of omeprazole is not significantly altered in patients with reduced renal function. Therefore, dose adjustment is not required.

Renal Insufficiency
The systemic bioavailability of omeprazole is not significantly altered in patients with reduced renal function. Therefore, dose adjustment is not required.

Hepatic Insufficiency
The area under the plasma concentration-time curve is increased in patients with impaired liver function, but no tendency to accumulation of omeprazole has been found.

5.3 Preclinical Safety Data:
Gastric ECL-cell hyperplasia and carcinoids, have been observed in life-long studies in rats treated with omeprazole. These changes are the result of sustained hypergastrinaemia secondary to acid inhibition. Similar findings have been made after treatment with H2-receptor antagonists, proton pump inhibitors and after partial fundectomy. Thus, these changes are not from a direct effect of any individual active substance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

EGC Risek Capsule 20mg Size “2” printed “Getz logo” and “RSK-20”.

6.2 Incompatibilities

None

6.3 Shelf-life
3 years
The expiration dates refers to the product correctly stored in the required conditions.

6.4 Special precautions for storage

- Do not store above 30℃.
- Protect from sunlight & moisture.
- Keep out of reach of children.

6.5 Nature and contents of container

Getzome (Omeprazole) Capsules 20mg are available in Alu-Alu blister Pack of 2 x 7’s.

6.6 Instructions for use/handling

Keep out of reach of children.
To be dispensed on prescription only.

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Getz Pharma (Private) Limited
29-30/27, Korangi Industrial Area Karachi 74900, Pakistan
Tel: (92-21) 111 111 511
Fax: (92-21) 505 7592

8. DRUG PRODUCT MANUFACTURER

Getz Pharma (Private) Limited
29-30/27, Korangi Industrial Area Karachi 74900, Pakistan
Tel: (92-21) 111 111 511
Fax: (92-21) 505 7592

9. NAFDAC REGISTRATION NUMBER

A4-9554