SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GENERIC: Omeprazole Delayed Release Capsules USP 20mg
BRAND NAME: OMESK

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard gelatin capsule contains:
Omeprazole USP …… 20 mg
(as enteric coated pellets)
Excipients ….....…..q.s
Approved colours used in empty shells.

3. PHARMACEUTICAL FORM:

Solid Oral Dosage Form – Capsules.

Plain hard gelatin capsules of size '2' having pink Cap and white BODY without any spots on the surface. Containing white to off white enteric coated omeprazole pellets.

4.CLINICAL PARTICULARS

4.1 Therapeutic Indication:

Duodenal Ulcer: Omeprazole capsules are indicated for short-term treatment of active duodenal ulcer. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

Treatment gastroesophageal reflux disease (gerd): Omeprazole capsules are indicated for the treatment of heartburn and other symptoms associated with gerd.

Erosive esophagitis : omeprazole capsules are indicated for the short term (4 to 8 weeks) of erosive esophagitis which has been diagnosed by endoscopy. The efficacy of omeprazole used for longer than 8 weeks of treatment, it may be helpful to give up to an additional 4 weeks of treatment. If there is recurrence of erosive esophagitis or gerd symptoms, additional 4-8 weeks courses of omeprazole may be considered.

Maintenance of healing of erosive esophagitis: omeprazole capsules are indicated to maintain healing of erosive esophagitis. Controlled studies do not extend beyond 12 months.

Pathological hypersecretory conditions: Omeprazole capsules are indicated for the long-term treatment of pathological hypersecretory conditions (e.g. Zollinger-Ellison syndrome, multiple endocrine adenomas and systemic mastrocytosis).

4.2 Posology and method of administration:

As directed by the physician.

Method of administration

Orally. Omeprazole capsules should be swallowed whole and not opened, chewed or crushed.

4.3 Contraindications:

Omeprazole capsules are contraindicated in patients with known hypersensitivity to any component of the formulation.

4.4 Warning and precautions for use

General symptomatic response to therapy with omeprazole doesnot preclude the presence of gastric malignancy. Atrophic has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole. Information for patients omeprazole capsules should be taken before eating. Patients should be cautioned that the omeprazole capsules should not be opened, chewed or crushed, and should be swallowed whole.

4.5 Drug Interactions

Other omeprazole can prolong elimination of diazepam, warfarin and phenytoin, drugs that are metabolized by oxidation in the liver. Although in normal subjects no interaction with theophylline or propranolol was found, there have been clinical reports of interaction with other drugs metabolized via the cytochrome p-450 system (e.g. cyclosporine, disulfiram, benzodiazepines)-patients should be monitored to determine if it is necessary to adjust the dosage of these drugs when taken concomitantly with omeprazole capsules. Because of its profound and long-lasting inhibition of gastric acid secretion, it is theoretically possible that omeprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bioavailability (e.g. ketoconazole, ampicillin esters and iron salts.

In the clinical trials, antacids were used concomitantly with the administration of omeprazole.

Paediatric use: safety and effectiveness in children have not been established.

4.6 Fertility Pregnancy & Lactation

Pregnant: teratology studies conducted in pregnant rats at doses up to 138 mg/kg/day (approximately 172 times the human dose) did not disclose any evidence for a teratogenic potential of omeprazole.

Nursing mothers: It is not known whether omeprazole is excreted in human milk. In rats, omeprazole administration during late gestation and lactation at doses of 13.8 to 138 mg/kg/day (3.4

to 34 times the human dose) resulted in decreased weight gain in pups. Because many drugs are excreted in human milk, because of the potential for serious adverse reaction in nursing infants from omeprazole 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:

None stated.

4.8 Adverse Effects

Omeprazole capsules were generally well –tolerated during domestic and international clinical trials in patients. In the U.S, clinical trial patients (including duodenal ulcer, Zollinger-Ellison syndrome and resistant ulcer patients, the following adverse experiences were reported to occur in 1% or more of patients on therapy with omeprazole capsules.

Numbers in parentheses indicate percentages of the adverse experiences considered by investigators as possibly, probably or definitely to the drug.

4.9 Overdose

Rare reports have been received of overdosage with omeprazole. Dose ranged from 320 mg to 900 mg (16-45 times the usual recommended clinical dose).

Manifestations were variable, but included confusion, drowsiness, blurred vision, tachycardia, nausea, diaphoresis, flushing headache and dry mouth. Symptoms were transistent and no serious clinical outcome has been reported. No specific antidote for omeprazole overdosage is known. Omeprazole is extensively protein bound and is, therefore, not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive. Lethal doses of omeprazole after single oral administration are about 15000 mg/kg in mice and greater than 40 mg/kg in rats given single intravenous infections. Animals given these doses showed sedation, ptosis, convulsions and decreased activity, body temperature and respiratory rate and increased depth of respiration.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Proton pump inhibitors.

Mechanism of action:

Omeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H^+/K^+-ATPase in the gastric parietal cell. By acting specifically on the proton pump, omeprazole blocks the final step in acid production, thus reducing gastric acidity.

5.2 Pharmacokinetic properties

Absorption

Omeprazole are acid labile and are therefore administered orally as enteric-coated pellets in capsules. Absorption of omeprazole is rapid, with peak plasma levels occurring approximately 1-2 hours after dose. Absorption of omeprazole takes place in the small intestine and is usually completed within 3-6 hours. Concomitant intake of food has no influence on the bioavailability. The systemic availability (bioavailability) from a single oral dose of omeprazole is approximately 40%. After repeated once-daily administration, the bioavailability increases to about 60%.

Distribution

The apparent volume of distribution in healthy subjects is approximately 0.3 L/kg body weight. Omeprazole is 97% plasma protein bound.

Metabolism

Omeprazole is completely metabolised by the cytochrome P450 system (CYP). The major part of its metabolism is dependent on the polymorphically expressed CYP2C19, responsible for the formation of hydroxyomeprazole, the major metabolite in plasma. The remaining part is dependent on another specific isoform, CYP3A4, responsible for the formation of omeprazole sulphone. As a consequence of high affinity of omeprazole to CYP2C19, there is a potential for competitive inhibition and metabolic drug-drug interactions with other substrates for CYP2C19. However, due to low affinity to CYP3A4, omeprazole has no potential to inhibit the metabolism of other CYP3A4 substrates. In addition, omeprazole lacks an inhibitory effect on the main CYP enzymes.

Approximately 3% of the Caucasian population and 15-20% of Asian populations lack a functional CYP2C19 enzyme and are called poor metabolisers. In such individuals the metabolism of omeprazole is probably mainly catalysed by CYP3A4. After repeated once-daily administration of 20 mg omeprazole, the mean AUC was 5 to 10 times higher in poor metabolisers than in subjects having a functional CYP2C19 enzyme (extensive metabolisers). Mean peak plasma concentrations were also higher, by 3 to 5 times. These findings have no implications for the posology of omeprazole.

Excretion

The plasma elimination half-life of omeprazole is usually shorter than one hour both after single and repeated oral once-daily dosing. Omeprazole is completely eliminated from plasma between doses with no tendency for accumulation during once-daily administration. Almost 80% of an oral dose of

omeprazole is excreted as metabolites in the urine, the remainder in the faeces, primarily originating from bile secretion.

The AUC of omeprazole increases with repeated administration. This increase is dose-dependent and results in a non-linear dose-AUC relationship after repeated administration. This time- and dose-dependency is due to a decrease of first pass metabolism and systemic clearance probably caused by an inhibition of the CYP2C19 enzyme by omeprazole and/or its metabolites (e.g. the sulphone).

No metabolite has been found to have any effect on gastric acid secretion.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule consist of gelatin

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months

6.4 Special precautions for storage:

Store between 15 ºC to 30°C. Protect from light.

Keep the medicine out of reach of children.

6.5 Nature and contents of container

10 capsules in an Aluminium- Aluminium strip pack & such 10 strips in a carton along with insert.

7. APPLICANT

Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.

8. NATIONAL REGISTRATION NUMBER

07265/09517/NMR/2022

9. DATE OF AUTHORISATION

11/04/2022

10. DATE OF REVISION OF THE TEXT

July 2023