1. NAME OF THE MEDICINAL PRODUCT

Omeprazole Delayed Release Capsules USP 20mg

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

For complete list of excipients refer section 6.1

3. PHARMACEUTICAL FORM

Solid Oral Dosage Form- Capsules.

4. Clinical particulars

4.1 Therapeutic indications

CYGNUS is indicated in the treatment of duodenal ulcer, gastric ulcer and reflux oesophagitis. It is also used for the control of acid secretion in the pathological hypersecretory conditions e.g. Zollinger-Ellison syndrome.

4.2 Posology and method of administration

Do not chew or crush the capsules.

Duodenal ulcer /Gastric ulcer: CYGNUS 20 mg once daily 2-4 weeks.

Reflux Oesophagitis: CYGNUS 20mg once daily for 4-8 weeks

Pathological hypersecretory conditions:

The recommended initial dose of Omeprazole in these patients is 60 mg once daily. Dosages should be individualized and should be continued for as long as clinically indicated. Dosages higher than 80mg/day should be administered in divided doses.

No dosage adjustment is necessary for patients with renal impairment, hepatic dysfunction or the elderly.

4.3 Contraindications

CYGNUS is contraindicated in patients with known hypersensitivity to the drug.

4.4 Special warnings and precautions for use

Symptomatic response to CYGNUS therapy does not preclude the presence of gastric malignancy.

Unless benefits of the treatment outweigh the possible risks, the use of CYGNUS in the pregnant and lactating women is not recommended since there are no adequate or well controlled studies regarding the usage of Omeprazole in such patients. Safety and effectiveness of Omeprazole in children has also not been established.

4.5 Interaction with other medicinal products and other forms of interaction

Monitoring of patients taking diazepam, warfarin and phenytoin concomitantly with CYGNUS is recommended to determine whether it is necessary to adjust the dosage of these drugs.

CYGNUS may interfere the metabolism of drugs metabolised by cytochrome 450 enzyme system. No interaction with concomitantly administered antacids has been found.

4.6 Pregnancy and Lactation

Pregnant: Teratology studies conducted in pregnant rates at doses upto 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 for 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 made whether to discontinue nursing or to discontinue drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines

Omeprazole is not likely to affect the ability to drive or use machines. Adverse drug reactions such as dizziness and visual disturbances may occur. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

CYGNUS is well tolerated. Nausea, headache, diarrhoea, constipation and flatulence have been reported occasionally. Rarely skin rash has occurred in a few patients. These effects are mild and transient and bear no consistent relationship with treatment.

4.9 Overdose

Rare reports have been received of overdosage with Omeprazole. Doses range 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 1500 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 Pharmacodynamics properties

Mechanism of action

Pharmacotherapeutic group: Drugs for acid-related disorders, proton pump inhibitors, ATC code: A02BC01

CYGNUS (Omeprazole) is substituted benzimidazole derivative which markedly inhibits basal and simulated gastric acid secretion by a unique mode of action specifically blocking the H+/K+ ATPase enzyme system of the gastric parietal cell (the so called proton pump)

which is the terminal step in the acid secretory pathway. It is a quick onset of action when the drug is discontinued, secretory activity returns gradually over 3 to 5 days

5.2 Pharmacokinetic properties

Omeprazole is rapidly absorbed, but to a variable extent ,following oral administration.

Absorption of Omeprazole is not affected by food but is dose dependent. Bioavailability of Omeprazole may be increased in elderly patients, in some ethic groups such as Chinese ,and in patient with impaired hepatic function, but is markedly affected in patient with renal impairment. Following absorption Omeprazole is almost completely metabolised in the liver by cytochrome P 450 isoforms and rapidly eliminated, mostly in urine. Although the elimination half life from plasma is short ,being reported to about 0.5 to 3 hours, its duration of action with regards to inhibition of acid secretion is much longer allowing it to be used in single daily dose. Omeprazole is highly bound (about 95%) to plasma protein.

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

Capsule consist of gelatin

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store between 15°C and 30°C in dry place. Protect from light.

Keep the medicine out of reach of children.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

7 capsules in a strip, such 2X7 strips in a printed carton with a printed insert..

6.6 Special precautions for disposal <and other handling>

Any unused product or waste material should be disposed of in accordance with local requirements

7. APPLICANT/MANUFACTURER>

Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,
Vapi - 396 195. Gujarat, INDIA.