SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:

1.1 Product Name
OMEZOLE 20MG CAPSULE

1.2 International Non-Proprietary Name
OMEPRAZOLE 2OMG CAPSULE

1.3 Dosage
Solid Dosage Form

1.4 Pharmaceutical Dosage Form
Capsule

1.5 Pharmacological Class
Proton pump inhibitors

1.6 Presentation
Blister of 4 x 7's

2. Quality and Quantitative Composition:

No.	Name of Ingredient	mg/capsule	Function	Reference monograph
Active ingredient				
1	Omezole	20.00	Active ingredient	USP

3. Pharmaceutical Form

Light caramel opaque and flesh opaque capsule with “OMEZOLE 20”printed on one end and “hovid” on the other end of the capsules.

4. Clinical Particulars

4.1 Therapeutic Indications

Omeprazole is indicated for:

- treatment of reflux oesophagitis.
- duodenal ulcer; benign gastric ulcer.
- long term treatment of pathologic gastric hypersecretion associated with Zollinger-Ellison syndrome.

4.2 Contraindications

Contraindicated in patients known to be hypersensitive to omeprazole.

4.3 Posology and Method of Administration

Omezole capsules are recommended to be taken immediately before meals, preferably in the morning and swallowed whole with liquid. For patients with swallowing difficulties the capsule might be opened and the contents swallowed or suspended in a slightly acidic fluid e.g juice, soured milk, or non-carbonated water. The dispersion should be taken immediately or within 30 minutes. Alternatively patients can suck the capsule and swallow the pellets with liquid. The pellets must not be chewed or crushed.

Usual adult and adolescent dose:

- **Reflux Oesophagitis**

  The recommended dosage is Omezole 20 mg once daily. Symptom resolution is rapid and in most patients healing occurs within 4 weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further 4 weeks treatment period. In patients with severe reflux oesophagitis, Omezole 40 mg once daily is recommended and healing is usually achieved within 8 weeks.

- **Duodenal Ulcer/ Benign Gastric Ulcer**
  Oral, 20 mg once a day. The dosage can be increased to 40 mg once a day for duodenal/gastric ulcer refractory to other treatment regimens. If healing of gastric ulcer has not occurred within 4 weeks, an additional 4 weeks of treatment is recommended. Long term therapy for patients with history of recurrent duodenal ulcer is recommended at a dosage of 20 mg Omezole once daily, up to one year.
- **Gastric hypersecretory (e.g., Zollinger-Ellison)**
  Oral, 60 mg once a day, the dosage being adjusted as needed, and therapy continued for as long as clinically indicated. Dose adjustment is not required in the elderly.
- **Impaired renal function**
  Dose adjustment is not required in patients with impaired renal function.
- **Impaired hepatic function**
  As bioavailability and plasma half-life of omeprazole are increased in patients with impaired hepatic function, a daily dose of 20 mg may be sufficient.

4.4 Special Warning and Precautions for Use

- Before giving omeprazole to patients with gastric ulcers the possibility of malignancy should be considered since omeprazole may mask symptoms and delay diagnosis.
- Omeprazole is extensively metabolised in the liver and some sources recommended that dosage should be reduced in hepatic impairment.
- Risk-benefit should be considered when the following medical problems exist: chronic, current or history of hepatic disease where dosage reduction may be required due to increased half-life.

4.5 Drug Interaction

- Since omeprazole may increase gastrointestinal pH, concurrent use with ampicillin esters, iron salts or ketoconazole may result in a reduction in absorption of these medications.
- Inhibition of the cytochrome P-450 enzyme system by omeprazole, especially in high doses, may cause a decrease in the hepatic metabolism of anticoagulants (coumarin or indandione-derivative) or diazepam or phenytoin, which may result in delayed elimination and increased blood concentrations, when these medications are used concurrently with omeprazole.

- Concurrent use of omeprazole with bone marrow depressants may increase the leukopenic and/or thrombocytopenic effects of both these medications; if concurrent use is required, close observation for toxic effects should be considered.

4.6 Pregnancy and lactation

- Adequate and well-controlled studies in humans have not been done. There is no evidence on the safety of omeprazole in human pregnancy. Animal studies have revealed no teratogenic effect, but reproduction studies have revealed reduced litter weights. Avoid in pregnancy unless there is no safer alternative.
- It is not known whether omeprazole is excreted in human milk. However, because omeprazole has been shown to cause tumorigenic and carcinogenic effects in animals, a decision should be made on whether nursing should be discontinued or the medication withdrawn, taking into account the importance of the omeprazole to the mother.

4.7 Effects on ability to drive and use machine

None known

4.8 Undesirable effects

- Cases of haematologic abnormalities, specifically anemia (unusual tiredness or weakness), eosinopenia, leukocytosis (sore throat and fever), neutropenia (continuing ulcers or sore in mouth), pancytopenia or thrombocytopenia (unusual bleeding or bruising), haematuria (bloody urine), proteinuria (cloudy urine), urinary tract infection (difficult, burning, or painful urination, frequent urge to urinate or bloody or cloudy urine).
- Abdominal pain and colic.
- Asthenia (unusual tiredness, muscle pain); central nervous system (CNS) disturbances, specifically dizziness, headache, somnolence (unusual drowsiness), or unusual tiredness; chest pain; gastrointestinal disturbances, specifically acid regurgitation (heartburn), constipation, diarrhoea or loose stools, flatulence (gas), or nausea and vomiting; skin rash or itching.

4.9 Overdose

Clinical features:

No information available on the effects of overdosage in man.

Treatment for overdosage:

Since there is no specific antidote, treatment should be symptomatic and supportive.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Omeprazole is activated at an acidic pH to a sulphenamide derivative that binds irreversibly to H+/K+ ATPase, an enzyme system found at the secretory surface of parietal cells. It thereby inhibits the final transport of hydrogen ions (via exchange with potassium ions) into the gastric lumen. Since the H+/K+ ATPase enzyme system is regarded as the acid (proton) pump of the gastric mucosa, omeprazole is known as a gastric acid pump inhibitor. Omeprazole inhibits both basal and stimulated acid secretion irrespective of the stimulus.

5.2 Pharmacokinetic Properties

Omeprazole is rapidly absorbed, but not to a variable extent, following oral administration. Absorption of omeprazole is not affected by food. The absorption of omeprazole, as well as being formulation-dependent, also appears to be dose-dependent, as increasing dosage above 40 mg has been reported to increase the plasma concentrations in a non-linear fashion. Following absorption, omeprazole is almost completely metabolised in the liver, primarily by cytochrome P450 isoform CYP2C19. It is eliminated 72 to 80% through renal and 18 to 23% through fecal. In dialysis, it is not readily dialyzable because of extensive protein binding.

5.3 Preclinical Safety Data

None known

6. Pharmaceutical Particulars

6.1 Incompatibilities

Not applicable

6.2 Shelf life

3 years from date of manufacture

6.3 Special precautions for storage

Store below 25°C. Protect from moisture.

6.4 Nature and Contents of Container

Descriptions of each packaging material for Omezole 20 mg Capsule are as below:

Immediate Container/Packaging

Blister Pack

Type

Push-through Aluminium-Aluminium blister pack; the package consists of cold form blister foil material and a heat-sealed, lacquered backing material

Cold Form Blister Foil

Description	: Multilayer cold-formable aluminium based blister film, with composition of nylon / Aluminium / PVC
Thickness	: 0.126 – 0.154 mm
Grammage	: 2.16-2.64 g/100 cm^2

Aluminium blister foil

Description	: Aluminium foil with high slip primer on bright surface and heat seal on matt surface/Aluminium foil with high slip primer on matt surface and heat seal on bright surface
Composition	: Print primer – Hydroxy functionalized acrylic polymer Aluminium foil 25 µm – Metal composition of Aluminium > 99.0%, Si (0.3-1.1%), Ferum (0.4-1.0%), Copper < 0.05%, Manganese < 0.05%, Chromium < 0.02%, Zinc < 0.07%, Titanium < 0.03% Heat seal lacquer – Solid methacrylic copolymer/vinyl copolymer

Appearance	: Bright surface/Matt surface each side
Heat Seal Lacquer Presence	:Heat Seal Lacquer surface is present on plain surface of the foil
Thickness	: 27 - 33 micron
Grammage	: 65.0 – 78.0 gsm

Secondary Packaging Components

Outer Container/Packaging
Type: Unit box
Material: Paper carton

7. Marketing Authorisation Holder

Name **:** Hovid Bhd.
Address **:** 121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar), 30100 Ipoh, Perak, Malaysia.

8. Manufacturer and Manufacturing Site

Name **:** Hovid Bhd.
Address **:** Lot 56442, 7 ½ Miles, Jalan Ipoh/Chemor, 30010 Chemor, Perak, Malaysia.

9. Date of First Authorisation / Renewal of the Authorisation

NIL

10. Date of Revision of Text

May 2019