SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : Prohibin Capsule

1.2 Generic Name : Gatro-resistant Omeprazole Capsules BP

1.3 Strength : 20mg per capsule

1.4 Pharmaceutical Form: Capsule

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each hard gelatine capsule Contains:

Omeprazole BP 20 mg

(as enteric coated pellets)

Approved colours used in the shell

3. PHARMACEUTICAL FORM

Capsule

Pink, coloured, transparent hard gelatin intact capsule of size "2", packed in Alu-Alu strips or Al/PVC blister with inner carton.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Omeprazole is used to treat symptoms of gastro-esophageal reflux disease (GERD) and other conditions caused by excess stomach acid. It is also used to promote healing of erosive esophagitis (damage to your esophagus caused by stomach acid). Omeprazole may also be given together with antibiotics to treat gastric ulcer caused by infection with Helicobacter pylori (H. pylori). Over-the-counter (OTC) omeprazole is used to help control heartburn that occurs 2 or more days per week.

4.2 Posology and method of administration

By Mouth

- **Helicobacter pylori eradication** in combination with amoxicillin and clarithromycin; or in combination with amoxicillin and metronidazole; or in combination with clarithromycin and metronidazole.

  Adult: 20 mg twice daily.

- **Eradication failure of Helicobacter pylori infection** in combination with tripotassium dicitratobismuthate, tetracycline and metronidazole.
  Adult: 20 mg twice daily.
- **Benign gastric ulceration**
  Adult: 20 mg once daily for 8 weeks, increased if necessary to 40 mg once daily, in severe or recurrent cases.·
- **Duodenal ulceration**
  Adult: 20 mg once daily for 4 weeks, increased if necessary to 40 mg once daily, in severe or recurrent cases.
- **Prevention of relapse in gastric ulcer**
  Adult: 20 mg once daily, increased if necessary to 40 mg once daily.
- **Prevention of relapse in duodenal ulcer**
  Adult: 20 mg once daily, dose may range between 10–40 mg daily.
- NSAID-associated duodenal ulcer , NSAID-associated gastric ulcer , NSAID-associated gastroduodenal erosions.
  Adult: 20 mg once daily for 4 weeks, continued for a further 4 weeks if not fully healed.
- **Prophylaxis in patients with a history of NSAID-associated duodenal ulcer** who require continued NSAID treatment.
- **Prophylaxis in patients with a history of NSAID-associated gastric ulcer** who require continued NSAID treatment.
- **Prophylaxis in patients with a history of NSAID-associated astroduodenal lesions** who require continued NSAID treatment.
- **Prophylaxis in patients with a history of NSAID-associated dyspeptic symptoms** who require continued NSAID treatment.
  Adult: 20 mg once daily.
- **Gastro-oesophageal reflux disease**
  Adult: 20 mg once daily for 4 weeks, continued for a further 4–8 weeks if not fully healed; maintenance 20 mg once daily.
- **Gastro-oesophageal reflux disease refractory to other treatment**
  Adult: 40 mg once daily for 8 weeks; maintenance, 20 mg once daily.
- **Acid reflux disease. (long-term management)**
  Adult: 10 mg once daily, increased to 20 mg once daily, dose only increased if symptoms return.
- **Acid-related dyspepsia**
  Adult: 10–20 mg once daily for 2–4 weeks according to response.
- **Zollinger–Ellison syndrome**
  Adult: Initially 60 mg once daily; usual dose 20–120 mg daily, total daily doses greater than 80 mg should be given in 2 divided doses.
- **Treatment of major peptic ulcer bleeding** (following endoscopic treatment) is an unlicensed indication.

4.3 Contraindications:

Omeprazole is contraindicated in patients with known hypersensitivity to Omeprazole. When gastric ulcer is suspected, the possibility of malignancy should be excluded before treatment with Omeprazole is instituted, as treatment may alleviate symptoms and delay diagnosis.

4.4 Special warnings and special precautions for use:

Severe hypomagnesaemia has been reported in patients treated with PPIs like omeprazole for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur but they may begin insidiously and be overlooked. In most affected patients, hypomagnesaemia improved after magnesium replacement and discontinuation of the PPI. Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter. As in all longterm treatments, especially when exceeding a treatment period of 1 year, patients should be kept under regular surveillance. Some children with chronic illnesses may require long term treatment although it is not recommended.

4.5 Interaction with other FPPs and Other forms of Interaction

Antibacterials: Plasma concentration of both drugs increased when Omeprazole given with Clarithromycin.
Anticoagulants: Omeprazole possibly enhance anticoagulant effect of Coumarins.
Antidepressants: Omeprazole increases plasma concentration of Escitalopram.
Antiepileptics: Plasma concentration of omeprazole increased by Voriconazole.
Antipsychotics: Omeprazole possibly reduces plasma concentration of Clozapine.
Antivirals: Omeprazole increases plasma concentration of Raltegravir.
Anxiolytics and Hypnotics: Omeprazole possibly inhibit metabolism of Diazepam (increased plasma concentration).
Cilostazol: Omeprazole increases plasma concentration of Cilostazol.
Clopidogrel: Omeprazole reduce antiplatelet effect of Clopidogrel.
Erlotinib: Omeprazole reduces plasma concentration of Erlotinib.
Tacrolimus: Omeprazole possibly increases plasma concentration of Tacrolimus.

4.6 Pregnancy and lactation

Pregnancy: No adverse effects of omeprazole on pregnancy or on the health of the foetus/newborn child. Omeprazole can be used during pregnancy.
Breast feeding: Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

The side effects are headache, stomach pain, nausea, diarrhea, vomiting, gas & Fever.

Adverse Effects: Adverse Effect of omeprazole are as skin reactions, gynecomastia, impotence or an increase of transaminases. Isolated cases of neuromyopathies, peripheral neuropathies, interstitial nephritis and liver failure have been observed.

4.9 Overdose

There is limited information available on the effects of overdoses of omeprazole in humans the doses of up to560 mg have been described, and occasional reports have been received when single oral doses have reached upto 2,400mg omeprazole (120 times the usual recommended clinical dose). Nausea, vomiting, dizziness, abdominal pain, diarrhoeaand headache have been reported. Also apathy, depression and confusion have been described in single cases. The symptoms described have been transient, and no serious outcome has been reported. The rate of elimination was unchanged (first order kinetics) with increased doses. Treatment, if needed, is symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Proton pump inhibitor

Mechanism of action:

Omeprazole, a racemic mixture of two enantiomers reduces gastric acid secretion through a highly targeted mechanism of action. It is a specific inhibitor of the acid pump in the parietal cell. It is rapidly acting and provides control through reversible inhibition of gastric acid secretion with once daily dosing.

Omeprazole is a weak base and is concentrated and converted to the active form in the highly acidic environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme H+/K +-AT Pase - the acid pump. This effect on the final step of the gastric acid formation process is dose-dependent and provides for highly effective inhibition of both basal acid secretion and stimulated acid secretion, irrespective of stimulus.

5.2 Pharmacokinetic properties

Absorption: Omeprazole are acid labile and are therefore administered orally as enteric-coated granules 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.

Biotransformation: Omeprazole is completely metabolized by the cytochrome P450 system (CYP).

Elimination: 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.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
01.	Non Pareil seeds	BP
02.	E. H. G. Capsules size "2" Pink/Pink	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at temperature not exceeding 30^0C.

6.5 Nature and contents of container

10 strips of 10 capsules each packed in an inner carton (10x10)

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER
06864/07496/REN/2020

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Nov 28, 2021

10. DATE OF REVISION OF THE TEXT
01/01/2023

11. DOSIMETRY (IF APPLICABLE)
Not applicable

12. INSTRUCTIONS FOR PREPARATION OFRADIOPHARMACEUTICALS (IF APPLICABLE)
Not applicable