

# OMELINZ<sup>®</sup> Capsules

(Omeprazole) 20mg

(Product Specs.: U.S.P.)

اومیلینز کپسول

## ENTERIC COATED PELLETS

### DESCRIPTION:

**Omelinz** (Omeprazole) is a proton pump inhibitor and prevents secretion of gastric acid through a highly sensitive mechanism of action. The onset of action is rapid and reversible. Control of gastric acid secretion is achieved with a once daily dose.

### COMPOSITION:

**Omelinz** is supplied as Capsules for oral administration.

**Omelinz** 20mg Capsule: Each Capsule Contains: Omeprazole (Prepared Pellets) ..... 20mg USP (Enteric Coated Pellets)

### INDICATIONS:

**Omelinz** (Omeprazole) is indicated for the treatment of:

Active duodenal ulcer.

Active benign gastric ulcer

Heartburn and other symptoms associated with GERD.

Erosive oesophagitis.

Zollinger-Ellison syndrome.

### CONTRAINDICATIONS:

**Omelinz** (Omeprazole) is contraindicated in patients with known hypersensitivity to any component of the formulation.

### PRECAUTIONS:

#### Information for the Patient.

**Omelinz** (Omeprazole) should be taken before eating. Patient should be cautioned that **Omelinz** (Omeprazole) capsule should not be opened, and should be swallowed whole. No dosage adjustment is necessary for patients with renal impairment, hepatic dysfunction or for the elderly. Before giving **Omelinz** (Omeprazole) to patients with gastric ulcer, the possibility of malignancy should be excluded, since **Omelinz** (Omeprazole) may mask the symptoms and delay diagnosis.

### USE IN PREGNANCY AND LACTATION:

**Pregnancy Category C:** **Omelinz** (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 **Omelinz** (Omeprazole) is excreted in human milk. 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.

### ADVERSE REACTIONS:

**Omelinz** (Omeprazole) is generally well tolerated but following adverse events are observed:

**Body as a Whole:** Fever, pain, fatigue, abdominal swelling.

**Cardiovascular:** Chest pain or angina, tachycardia, bradycardia, palpitation, elevated blood pressure, peripheral edema.

**Gastrointestinal:** Pancreatitis, anorexia, flatulence, fecal discoloration, mucosal atrophy of the tongue, dry mouth.

**Metabolic/Nutritional:** Hypoglycemia, weight gain.

**Musculoskeletal:** Muscle cramps, muscle weakness, joint pain, leg pain.

**Nervous System/Psychiatric:** Psychic disturbances including depression, aggression, Hallucinations, confusion, insomnia, nervousness, tremors, anxiety, dream abnormalities; vertigo.

**Respiratory:** Epistaxis, pharyngeal pain.

**Skin:** Rash Stevens-Johnson syndrome, skin inflammation, urticaria, angioedema, pruritus, alopecia, dry skin.

**Special Senses:** Tinnitus.

**Urogenital:** Interstitial nephritis, urinary tract infection, urinary frequency, elevated serum creatinine, proteinuria, hematuria, glycosuria, testicular pain, gynecostasia.

**Haematological:** Rare instances of pancytopenia, agranulocytosis, thrombocytopenia, neutropenia, anemia, leucocytosis, and hemolytic anemia have been reported.

### DOSAGE AND ADMINISTRATION:

**Reflux Oesophagitis:** The recommended dosage **Omelinz** (Omeprazole) 20mg once daily.

Symptoms 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 further 4 weeks treatment period. In patients with severe reflux oesophagitis **Omelinz** (Omeprazole) 40mg once daily is recommended and healing is usually achieved with in 8 weeks. For the long term management of patients with healed reflux oesophagitis the recommended dose is **Omelinz** (Omeprazole) 10mg once daily.

If needed the dose can be increased to **Omelinz** (Omeprazole) 20-40mg once daily.

**Severe reflux oesophagitis in children from one year and elder.**

The management of severe reflux oesophagitis should be diagnosed or recommended by a paediatrician or gastroenterologist.

**The recommended dosage regimen for healing is:**

Weight	Dosage
10 - 20 kg	<b>Omelinz</b> (Omeprazole) 10mg daily
> 20 kg	<b>Omelinz</b> (Omeprazole) 20mg daily

If needed dosage may be increased to 20mg and 40 mg respectively.

**Helicobacter pylori (Hp) eradication regimens in peptic ulcer disease:**

**Triple therapy regimens:** **Omelinz** (Omeprazole) 20mg, Amoxicillin 1g and Clarithromycin 500mg, all twice a day for one week.

Or **Omelinz** (Omeprazole) 20mg, Metronidazole 400mg (or Tinidazole 500 mg) and Clarithromycin

250mg, all twice a day for one week.

Or **Omelinz** (Omeprazole) 40 mg once daily with Amoxicillin 500mg and Metronidazole 400mg both three times a day for one week.

**Dual therapy regimens: Omelinz** (Omeprazole) 40-80 mg with Amoxicillin 1.5g daily in divided doses for two weeks. In clinical studies daily doses of 1.5-3 g of Amoxicillin have been used.

Or

**Omelinz** (Omeprazole) 40 mg once daily and Clarithromycin 500mg three times a day for two weeks.

To ensure healing in patients with active peptic ulcer disease, see further dosage recommendations for duodenal and gastric ulcer. In each regimen if the patient is still (Hp) positive, therapy may be repeated.

**Duodenal Ulcer:** The recommended dosage in patients with active duodenal ulcer is **Omelinz** (Omeprazole) 20mg once daily. Symptom resolution is rapid and in most cases healing occurs within 2 weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further 2-weeks treatment period, in patients with poorly responsive duodenal ulcer.

**Omelinz** (Omeprazole) 40mg once daily is recommended and healing is usually achieved within 4 weeks.

For NSAID-associated duodenal ulcers see "NSAID-Associated Gastroduodenal Lesions".

**Gastric Ulcer:** The recommended dosage is **Omelinz** (Omeprazole) 20mg 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 poorly responsive gastric ulcer **Omelinz** (Omeprazole) 40mg once daily is recommended and healing is usually achieved within 8 weeks. For the prevention of relapse in patients with poorly responsive gastric ulcer the recommended dose is **Omelinz** (Omeprazole) 20 mg once daily. If needed the dose can be increased to **Omelinz** (Omeprazole) 40 mg once daily.

For NSAID-associated gastric ulcers see "NSAID Associated Gastro duodenal Lesions".

**NSAID-Associated Gastroduodenal Lesions:** NSAID associated gastric ulcers, duodenal ulcers, gastroduodenal erosions in patients with continued NSAID treatment. The recommended dosage of **Omelinz** (Omeprazole) is 20mg once daily. Symptoms 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. For the prevention of NSAID-associated gastric ulcers, duodenal ulcers, gastroduodenal erosions and dyspeptic symptoms the recommended dosage of **Omelinz** (Omeprazole) is 20 mg once daily.

**Acid related dyspepsia:** For relief of symptoms in patients with epigastric pain/discomfort with or without heartburn the recommended dosage is **Omelinz** (Omeprazole) 20 mg once daily. The starting dose is usually 10mg daily and this can

be increased. If control of symptoms has not been achieved after 4 weeks treatment with **Omelinz** (Omeprazole) 20mg daily, further investigation is recommended.

**Zollinger-Ellison syndromes:** In patients with Zollinger-Ellison syndrome the dosage should be individually, adjusted and treatment continued as long as clinically indicated. The recommended initial dose is **Omelinz** (Omeprazole) 60mg daily. All patients with severe disease and inadequate response to other therapies have been effectively controlled and more than 90% of the patients maintained on doses of **Omelinz** (Omeprazole) 20-120mg daily. When doses exceed **Omelinz** (Omeprazole) 80mg daily, the dose should be divided and given twice daily.

**Impaired Renal Function:** Dose adjustment is not needed in patients with impaired renal function.

**Impaired Hepatic Function:** As bioavailability and plasma half-life of **Omelinz** (Omeprazole) are increased in patients with impaired hepatic function a daily dose of 10-20mg may be sufficient.

**Elderly:** Dosage adjustment is not needed.

#### DRUG INTERACTIONS:

**Omelinz** (Omeprazole) can prolong the 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 and benzodiazepines). Patients should be monitored to determine if it is necessary to adjust the dosage of these drugs when taken concomitantly with **Omelinz** (Omeprazole).

#### PRESENTATION:

**Omelinz 20mg :** Pack of 14's capsules.

#### INSTRUCTIONS:

- Protect from light and moisture, store at room temperature.
- Keep out of reach of children.

**WARNING:** To be sold on prescription of a registered medical practitioner only.

ہدایات :-

روشنی اور نمی سے محفوظ کرے کے درجہ حرارت پر رکھیں۔

بچوں کی پہنچ سے دور رکھیں۔

انتباہ:- صرف رجسٹرڈ میڈیکل پریکٹیشنر کے نسخے پر فروخت کے لیے۔

Manufactured by:

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