

OMEZ

ABPI

NAME OF MEDICINAL PRODUCT: OMEZ (Omeprazole Capsules IP 10/20 mg) Dosage Form and Strength: Each capsule contains omeprazole IP 10/20 mg as enteric coated granules.

THERAPEUTIC INDICATIONS: Omeprazole capsule is indicated in the short-term treatment of duodenal ulcer, gastric ulcer, reflux oesophagitis and in the management of Zollinger-Ellison syndrome.

DOSAGE AND ADMINISTRATION: Duodenal Ulcer: The recommended adult oral dose for the short-term treatment of duodenal ulcer is 20 mg once daily for 4 weeks. Sometimes the treatment may require an additional 4 weeks. Gastric Ulcer: The recommended adult dose is 40 mg once daily for 4 - 8 weeks. For prevention of relapse in patients with duodenal ulcer the recommended dose is Omeprazole 10mg, once daily, increasing to 20mg, once daily if symptoms return. For patients who are at risk from recurrent ulcer relapse i.e., those with Helicobacter pylori infection, younger patients (<60 years), patients whose symptoms persist for more than one year and smokers, long-term therapy should be initiated with omeprazole 20mg once daily, reducing to 10mg once daily, if necessary. Reflux oesophagitis: For the short-term treatment of reflux oesophagitis with only symptomatic gastroesophageal reflux disease (GERD) and no oesophageal lesions, the recommended adult dose is 20 mg once daily for 4 weeks. For patients with erosive oesophagitis and accompanying symptoms of GERD, the recommended dose is 20 mg once daily for 4-8 weeks. Omeprazole 40 mg/day can be used in patients with reflux oesophagitis refractory to other therapy. Healing usually occurs within 8 weeks. Patients can be continued at a dosage of 20 mg once daily. Maintenance of healing of erosive oesophagitis: The usual adult oral dose is 20 mg daily. Zollinger-Ellison syndrome: The recommended starting oral dose is 60 mg once daily. The doses can be varied with individual patient's need and treatment should be continued as long as clinically indicated. Doses up to 120 mg t.i.d have been administered. With doses above 80 mg daily, the dose should be divided and given twice daily. Omeprazole should be taken before food. **USE IN SPECIAL POPULATIONS:** Paediatric population: (1 to 16 years of age) Safety profile similar to that in adults, except that respiratory system events and fever were the most frequently reported reactions in pediatric studies. Older patients - No dosage adjustment is necessary for elderly patients. However, greater sensitivity of some older individuals cannot be ruled out. Renal insufficiency / dialysis - No dosage adjustment is necessary in patients with renal insufficiency. Hepatic impairment - Consider dose reduction, particularly for maintenance of healing of erosive esophagitis.

Further information available upon

request. Date: 30th January, 2020