

OMEZ DSR

ABPI

NAME OF MEDICINAL PRODUCT: OMEZ-DSR (Omeprazole and Domperidone capsule). **DOSAGE FORM AND STRENGTH:** Each capsule contains omeprazole IP 20 mg as enteric coated pellets and domperidone BP 30 mg as sustained release pellets and Excipient qs. **THERAPEUTIC INDICATIONS:** Omeprazole and Domperidone are indicated for the treatment duodenal ulcers and gastric ulcers, reflux or ulcerative oesophagitis, Zollinger-Ellison syndrome, NSAID-induced ulcers and for the treatment of Gastroesophageal Reflux Disease (GERD) not responding to omeprazole alone. **DOSAGE AND ADMINISTRATION:** The usually recommended dose is a one capsule once daily. **CONTRAINDICATIONS:** Hypersensitivity to any component of the formulation. Contraindicated in pregnancy and in neonates. **ADVERSE EFFECTS:** The most commonly reported adverse reactions are headache, diarrhea, abdominal pain, nausea, flatulence, asthma, back pain, fever, fatigue, malaise and increased risk of enteric infections due to reduced acid secretion. **WARNINGS AND PRECAUTIONS:** In patients with severe liver impairment, the liver enzymes should be monitored regularly during treatment with omeprazole, particularly on long term use. If a rise in liver enzymes is observed, the formulation should be discontinued. **DRUG INTERACTIONS:** Omeprazole can prolong the elimination of diazepam; warfarin and phenytoin, drugs that are metabolized by oxidation in the liver and may interfere with absorption of ketoconazole, ampicillin esters and iron salts. Further information available upon request. Date: January 30, 2020