Omez DSR plus ABPI

Composition: Enteric Coated Esomeprazole 40mg and Domperidone Sustained Release 30mg Capsules. **Indication:** Omez DSR is indicated for the treatment of adult patients with gastro esophageal reflux disease (GERD) not responding to esomeprazole alone. **Contraindications:** Omez DSR is contraindicated in patients with known hypersensitivity to Esomeprazole or other substituted benzimidazoles or to Domperidone or other dopamine antagonists or to any excipients used in the formulation. Omez DSR should not be used whenever stimulation of gastrointestinal motility might be dangerous such as in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation. Omez DSR is contraindicated in patients with prolactinoma (a prolactin releasing pituitary tumour). **Special warnings and precautions for use:** Carcinogenesis, Mutagenesis, Impairment of Fertility. Esomeprazole-Symptomatic response to Esomeprazole therapy does not exclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long term with omeprazole, of which Esomeprazole is an enantiomer. Domperidone was administered to mice for 18 months and rats for 24 months in carcinogenicity studies. No dose-related effects were observed except for an increased incidence of malignant mammary tumours at 25 times the maximum human dose in female mice and rats and an increased incidence of pituitary tumours at 25 times the maximum human dose in male rats. No evidence for mutagenic potential was seen in dominant lethal studies in male and female mice, micronucleus tests in female mice and female rats. a study of chromosomal aberrations in human lymphocytes, a sex-linked recessive lethal test on Drosophila melanogaster, and in the Ames metabolic activation test with Salmonella typhimurium. **Undesirable Effects** : Proton Pump Inhibitors associated Acute Kidney Injury: Acute kidney injury has been reported with the use of Proton pump inhibitors (PPIs) including Pantoprazole, Omeprazole, Lansoprazole, Esomeprazole, Rabeprazole etc. Esomeprazole-Common adverse events reported with Esomeprazole in clinical trials include headache, nausea, vomiting, diarrhoea, abdominal pain, flatulence, constipation and dry mouth. Other less commonly reported adverse effects include dizziness, insomnia, allergic reactions, asthenia, bowel irregularity, urticaria, etc. The incidence of treatment-related adverse events during 6-month maintenance treatment with Esomeprazole was similar to placebo. There were no differences in types of related adverse events seen during maintenance treatment up to 12 months compared to short-term treatment. Domperidone-The most frequent reactions to Domperidone are those related to elevated prolactin levels including breast tenderness, galactorrhoea, gynaecomastia and amenorrhoea. These effects are dose-related and gradually resolve after lowering the dose or discontinuing treatment. Other rarely reported adverse reactions include headache, diarrhoea, dizziness, mild and transient abdominal cramps, dry mouth and drowsiness. Rare allergic reactions, such as rash and urticaria, have also been reported. Extrapyramidal reactions occur very rarely in adults and usually resolve completely and spontaneously after cessation of treatment. **Dosage and Administration:** In patients with normal hepatic or renal function: Depending on the severity, 1 capsule of Esomeprazole 40mg + SR Domperidone 30mg orally once daily for upto 4 weeks. In patients with mild-to-moderate hepatic and renal impairment: 1 capsule of Esomeprazole Domperidone 30mg orally once daily for upto 4 weeks. Patients receiving Omez DSR should be evaluated on a weekly basis. Following clinical resolution, patients should be shifted to either a proton pump inhibitor or a prokinetic agent alone for maintenance therapy.