

DOMSTAL PLUS

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Abbreviated Prescribing information for DOMSTAL PLUS (Domperidone 30 mg and Omeprazole I.P. 20mg capsule) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Domperidone is a dopamine antagonist and anti-emetic, increase lower oesophageal pressure, antroduodenal motility and accelerate gastric emptying. Omeprazole is a substituted benzimidazole that inhibits gastric acid secretion. **INDICATION:** For relief of post-prandial symptoms of fullness, nausea, epigastric bloating and belching accompanied by epigastric discomfort and heartburn not responding to omeprazole alone. **DOSAGE AND ADMINISTRATION:** One capsule twice daily or as directed, do not take more than allowed maximum individual component dose. Maximum allowed dose for omeprazole is 40mg and for domperidone is 80mg. **CONTRAINDICATION:** In patients with known hypersensitivity to domperidone, substituted benzimidazoles or to any component of the formulation. In patients with prolactin-releasing pituitary tumour (prolactinoma), hepatic and/or renal impairment and when stimulation of gastric motility could be harmful (gastrointestinal haemorrhage, mechanical obstruction or perforation). Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, interstitial nephritis, and urticaria. **WARNINGS & PRECAUTIONS:** Use is not recommended during lactation, in infants. Risk of neurological side effects and in patients with hepatic or renal insufficiency. Concomitant use with potent CYP3A4 inhibitors ketoconazole is not recommended due to prolongation of QT interval. Symptomatic response to therapy with omeprazole does not preclude the presence of gastric malignancy. Risk of atrophic gastritis, acute interstitial nephritis and Clostridium difficile associated diarrhea. On prolonged therapy risk of cyanocobalamin (vitamin B-12) Deficiency, bone fracture and hypomagnesemia. Avoid concomitant use with clopidogrel and St. John's Wort or rifampin. DOMSTAL PLUS may interfere with diagnostic investigations for neuroendocrine tumors. Associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death. **DRUG INTERACTIONS:** Interacts with antiretroviral therapy (atazanavir, nelfinavir and saquinavir), ketoconazole, ampicillin esters, iron salts, erlotinib, digoxin, diazepam, warfarin, cyclosporine, disulfiram, benzodiazepines, voriconazole, cilostazol, rifampin, Clopidogrel, tacrolimus, clarithromycin, methotrexate, phenytoin and erythromycin when administered concomitantly. **ADVERSE REACTIONS:** Allergic reactions including anaphylaxis, agitation, nervousness, increased prolactin levels, extrapyramidal side effects, convulsion, ventricular arrhythmias, transient intestinal cramps, diarrhea, amenorrhoea, elevated liver enzymes, dry mouth, headache, abdominal pain, nausea, vomiting, flatulence, acid regurgitation, upper respiratory infection, constipation, dizziness, rash, asthenia, back pain, fever, chest pain or angina, tachycardia, bradycardia, elevated blood pressure, pancreatitis (some fatal), hepatic failure (some fatal), liver necrosis (some fatal), gastroduodenal carcinoids, hypocalcemia, hypoglycemia, hyponatremia, myalgia, epistaxis, pharyngeal pain, toxic epidermal necrolysis (some fatal), Stevens-Johnson syndrome, optic atrophy, anterior ischemic optic neuropathy, interstitial nephritis, gynecomastia and agranulocytosis (some fatal).

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

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(Additional information is available on request)