DOMSTAL RD/OMIZAC D

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

Abbreviated Prescribing information for DOMSTAL RD/OMIZAC D [Omeprazole and Domperidone Capsules I.P.]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Omeprazole:*** It is a specific inhibitor of the acid pump in the parietal cell. It is rapidly acting and provides control through reversible inhibition of gastric acid secretion with once daily dosing. ***Domperidone:*** Domperidone is a dopamine antagonist with anti-emetic properties, Domperidone does not readily cross the blood-brain barrier. In domperidone users, especially in adults, extrapyramidal side effects are very rare, but domperidone promotes the release of prolactin from the pituitary. Its anti-emetic effect may be due to a combination of peripheral (gastrokinetic) effects and antagonism of dopamine receptors in the chemoreceptor trigger zone, which lies outside the blood-brain barrier in the area postrema.

INDICATIONS: It is indicated for the treatment of Gastroesophageal Reflux Disease (GERD) 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 40 mg and for domperidone is 80 mg. For oral use only.

CONTRAINDICATION: Known hypersensitivity to omeprazole, domperidone or any of the excipients, Prolactin-releasing pituitary tumour (prolactinoma), when stimulation of the gastric motility could be harmful e.g in patients with gastrointestinal, haemorrhage, mechanical obstruction or perforation, In patients with moderate or severe hepatic impairment, in patients who have known existing prolongation of cardiac conduction intervals, particularly QTc, patients with significant electrolyte disturbances or underlying cardiac Diseases such as congestive heart failure. Co-administration with QT-prolonging drugs, co-administration with potent CYP3A4 inhibitors (regardless of their QT prolonging Effects). Omeprazole like other proton pump inhibitors (PPIs) must not be used concomitantly with nelfinavir.

WARNINGS & PRECAUTIONS: ***Omeprazole:*** In the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment may alleviate symptoms and delay diagnosis. Co-administration of atazanavir with proton pump inhibitors is not recommended. Omeprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo- or achlorhydria. When starting or ending treatment with omeprazole, the potential for interactions with drugs metabolised through CYP2C19 should be considered. As a precaution, concomitant use of omeprazole and clopidogrel should be discouraged. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur but they may begin insidiously and be overlooked. In most affected patients, hypomagnesaemia improved after magnesium replacement and discontinuation of the PPI. Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping Omeprazole. Increased Chromogranin a (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, omeprazole treatment should be stopped for at least 5 days before CgA measurements. ***Domperidone:*** Domperidone has been associated with prolongation of the QT interval on the electrocardiogram. Epidemiological studies showed that domperidone was associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death. Treatment with domperidone should be stopped if signs or symptoms occur that may be associated with cardiac arrhythmia, and the patients should consult their physician. The elimination half-life of domperidone is prolonged in severe renal impairment. The dose may also need to be reduced.

DRUG INTERACTIONS: ***Omeprazole:*** The plasma levels of nelfinavir and atazanavir are decreased in case of co-administration with omeprazole. Concomitant administration of omeprazole with atazanavir is not recommended. Digoxin with omeprazole in healthy subjects increased the bioavailability of digoxin by 10%. Clopidogrel with omeprazole resulting in a decreased exposure to the active metabolite of clopidogrel by an

average of 46% and a decreased maximum inhibition of (ADP induced) platelet aggregation by an average of 16%. Other active substances the absorption of posaconazole, erlotinib, ketoconazole and itraconazole is significantly reduced and thus clinical efficacy may be impaired. For posaconazole and erlotinib concomitant use should be avoided. ***Domperidone:*** The main metabolic pathway of domperidone is through CYP3A4. In vitro data suggest that the concomitant use of drugs that significantly inhibit this enzyme may result in increased plasma levels of domperidone. Increased risk of occurrence of QT-interval prolongation, due to pharmacodynamic and/or pharmacokinetic interactions.

ADVERSE REACTIONS: ***Omeprazole:*** Leukopenia, thrombocytopenia, Agranulocytosis, pancytopenia. Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock. Headache, Dizziness, paraesthesia, Taste disturbance. Blurred vision. Vertigo, Bronchospasm, Abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting, fundic gland polyps (benign), Dry mouth, stomatitis, gastrointestinal, candidiasis and Microscopic colitis, Increased liver enzymes, Hepatitis with or without jaundice, Hepatic failure, encephalopathy in patients with pre-existing liver disease, Dermatitis, pruritus, rash, urticarial, Alopecia, photosensitivity, Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN) and Subacute cutaneous lupus erythematosus, Fracture of the hip, wrist or spine, Arthralgia, myalgia, Muscular weakness, Interstitial nephritis Acute kidney injury Gynaecomastia, Malaise, peripheral oedema, Increased sweating. ***Domperidone:*** Anaphylactic reaction, Loss of libido, Anxiety, Nervousness, Somnolence, Headache, Convulsion, Sudden cardiac death, QTc prolongation, Dry mouth, Diarrhoea, Rash, Pruritus, Urticarial, Angioedema, Urinary retention, Galactorrhoea, Breast pain, Breast tenderness, Gynaecomastia, Amenorrhoea, Asthenia, Liver function test abnormal and Blood prolactin increased.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/DOMSTAL RD/ OMIZAC D 10 mg, 20mg/APR-2026/07/ABPI

(Additional information is available on request)