DOMSTAL MT

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

Abbreviated prescribing information for DOMSTAL MT 10 (Domperidone Dispersible Tablets)

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

PHARMACOLOGICAL PROPERTIES: 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. Animal studies, together with the low concentrations found in the brain, indicate a predominantly peripheral effect of domperidone on dopamine receptors.

INDICATION: For the treatment of gastric motality disorder etc.

DOSAGE AND ADMINISTRATION: *Dosage:* One 10mg tablet up to three times per day with maximum dose of 30 mg per day. *Administration:* It is recommended to take oral domperidone tablets before meals. If taken after meals, absorption of the drug is somewhat delayed.

CONTRAINDICATION: 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, at the exception of apomorphine, Co-administration with potent CYP3A4 inhibitors (regardless of their QT prolonging effects).

Known hypersensitivity to domperidone or any of the excipients, Prolactin-releasing pituitary tumour (prolactinoma.), When stimulation of gastric motility could be harmful e.g in patients gastro-intestinal haemorrhage, mechanical obstruction or perforation.

WARNINGS & PRECAUTIONS: Renal Impairment: The elimination half-life of domperidone is prolonged in severe renal impairment. For repeated administration, the dosing frequency of domperidone should be reduced to once or twice daily depending on the severity of the impairment. The dose may also need to be reduced. Cardiovascular effects: Domperidone has been associated with prolongation of the QT interval on the electrocardiogram. As per reported data, during post-marketing surveillance, there have been very rare cases of QT prolongation and torsades de pointes in patients taking domperidone. These reports included patients with confounding risk factors, electrolyte abnormalities and concomitant treatment which may have been contributing factors Reported epidemiological studies showed that domperidone was associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death. A higher risk was observed in patients older than 60 years, patients taking daily doses greater than 30 mg, and patients concurrently taking QT-prolonging drugs or CYP3A4 inhibitors. Domperidone should be used at the lowest effective dose in adults and adolescents 12 years of age and older. Domperidone is contraindicated in patients with known existing prolongation of cardiac conduction intervals, particularly QTc, in patients with significant electrolyte disturbances (hypokalaemia, hyperkalaemia, hypomagnesaemia), or bradycardia, or in patients with underlying cardiac diseases such as congestive heart failure due to increased risk of ventricular arrhythmia (see *Contraindications*). Electrolyte disturbances (hypokalaemia, hyperkalaemia, hypomagnesaemia) or bradycardia are known to be conditions increasing the proarrythmic risk. 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. Patients should be advised to promptly report any cardiac symptoms. Use with apomorphine Domperidone is contra-indicated with QT prolonging drugs including apomorphine, unless the benefit of the co-administration with apomorphine outweighs the risks.

DRUG INTERACTIONS: Azole antifungals, specifically oral ketoconazole, fluconazole or voriconazole, Bacterial infections, specifically erythromycin, clarithromycin, telithromycin, moxifloxacin, pentamidine (these are antibiotics), Heart problems or high blood pressure (e.g., amiodarone, dronedarone, quinidine, disopyramide, dofetilide, sotalol, diltiazem, verapamil), Psychoses (e.g., haloperidol, pimozide, sertindole), Depression (e.g., citalopram, escitalopram), Gastro-intestinal disorders (e.g., cisapride, dolasetron, prucalopride), Allergy (e.g., mequitazine, mizolastine), Malaria (in particular halofantrine) AIDS/HIV (protease inhibitors), Cancer (e.g., toremifene, vandetanib, vincamine), Certain other medicines (e.g., bepridil, diphemanil, methadone), Domperidone and apomorphine.

ADVERSE REACTIONS: *Common (may affect up to 1 in 10 people):* Dry mouth *Uncommon (may affect up to 1 in 100 people):* Lowering of sexual drive (libido) in men, Feeling anxious, Feeling drowsy, Headaches, Diarrhoea, Itchy skin, rash , Unusual production of breast milk in men and women, Painful or tender breasts, A general feeling of weakness, *Not known (Frequency cannot be estimated from the available data): Disorders of the cardiovascular system:* heart rhythm disorders (rapid or irregular heart beat). Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day. Domperidone should be used at the lowest effective dose. Feeling agitated or irritable, Feeling more nervous than usual, Abnormal eye movements, Inability to urinate, Breast enlargement in men, In women, menstrual periods may be irregular or stop, A blood test shows changes in the way your liver is working Some patients who have used Domperidone for conditions and dosages requiring longer term medical supervision have experienced the following unwanted effects, Restlessness; swollen or enlarged breasts, unusual discharge from breasts, irregular menstrual periods in women, difficulty breastfeeding, depression, and hypersensitivity.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)