DOMSTAL SUSPENSION

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

Abbreviated Prescribing information for DOMSTAL SUSP

(Domperidone oral Drops)

[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: ***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.

INDICATIONS: Indicated for treatment of gastric motality disorder etc**.**

DOSAGE AND ADMINISTRATION: Domperidone oral Drops is available in 30 ml bottle pack.

CONTRAINDICATION: Domperidone is contraindicated in the following situations: Known hypersensitivity to 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 gastro-intestinal 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, at the exception of apomorphine, co-administration with potent CYP3A4 inhibitors (regardless of their QT prolonging effects).

WARNINGS & PRECAUTIONS*:* *Cardiovascular effects*: Domperidone has been associated with prolongation of the QT interval on the electrocardiogram. 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.Epidemiological studies showed that domperidone was associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death (see section 4.8). 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. *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, and only if the recommended precautions for co-administration mentioned in the apomorphine SmPC are strictly fulfilled. Please refer to the apomorphine SmPC.*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, and the dose may need to be reduced. Such patients on prolonged therapy should be reviewed regularly.

DRUG INTERACTIONS: Antacids or antisecretory agents should not be taken simultaneously with oral formulations of domperidone as they lower the oral bioavailability of domperidone. Domperidone should be taken before meals and antacids or antisecretory agents after meals. *Concomitant use of the following substances is contraindicated* : QTc prolonging medicinal products anti-arrhythmics class IA

(e.g., disopyramide, hydroquinidine, quinidine), certain anti-psychotics (e.g., haloperidol, pimozide, sertindole), certain anti-depressants (e.g., citalopram, escitalopram), certain antibiotics (e.g. , erythromycin, levofloxacin, moxifloxacin, spiramycin), certain antifungal agents (e.g., pentamidine) etc. protease inhibitors, systemic azole antifungals, some macrolides (erythromycin, clarithromycin, telithromycin) *Concomitant use of the following substances is not recommended*: Moderate CYP3A4 inhibitors i.e. diltiazem, verapamil and some macrolides. *Concomitant use of the following substances requires caution in use* : Caution with bradycardia and hypokalaemia-inducing drugs, as well as with the following macrolides involved in QT-interval prolongation: azithromycin and roxithromycin (clarithromycin is contra-indicated as it is a potent CYP3A4 inhibitor).

ADVERSE REACTIONS: ***Immune system disorders:*** Anaphylactic reaction. ***Psychiatric disorders:*** Loss of libido, Anxiety, Agitation,Nervousness. ***Nervous system disorders:*** Somnolence, Headache, Convulsion, Extrapyramidal disorder. ***Eye disorders:*** Oculogyric crisis. ***Cardiac disorders:*** Ventricular arrhythmias, Sudden cardiac death, QTc prolongation, Torsade de Pointes. ***Gastrointestinal disorders:*** Dry mouth, Diarrhoea. ***Skin and subcutaneous tissue disorder:*** Rash, Pruritus, Urticaria, Angioedema ***Renal and urinary disorders:*** Urinary retention. ***Reproductive system and breast disorders:*** Galactorrhoea, Breast pain, Breast tenderness. ***General disorders and administration site conditions:*** Asthenia. ***Investigations:*** Liver function test abnormal, Blood prolactin increased.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

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(Additional information is available on request)