

DOMSTAL BABY

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

Abbreviated Prescribing information for DOMSTAL BABY [Domperidone oral Drops]
[Please refer the complete prescribing information available at www.torrentpharma.com]

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 in the treatment of gastric motility disorder etc

DOSAGE AND ADMINISTRATION: 0.2 – 0.4 mg/kg body weight. Each drop contains approximately 0.4 mg of Domperidone or as directed by physician.

CONTRAINDICATION: 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: 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: *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: Anaphylactic reaction, loss of libido, anxiety, agitation, nervousness, somnolence, headache, convulsions, extrapyramidal disorder, oculogyric crisis, ventricular arrhythmias, sudden cardiac death, QTc prolongation, torsade de pointes, dry mouth, diarrhoea, rash, pruritus, urticaria, angioedema, urinary retention, galactorrhoea, breast pain, breast tenderness, gynaecomastia, amenorrhoea, sthenia, liver function test abnormal, blood prolactin increased.

MARKETED BY:

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PHARMA

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IN/DOMSTAL BABY 5ml/FEB-2022/03/ABPI

(Additional information is available on request)