DOMPERIDONE

TORIDON

10mg Dispersible Tablet
Gastro-kinetic/Prokinetic

FORMULATION
Each dispersible tablet contains:
Domperidone ..... 10 mg
PRODUCT DESCRIPTION
Domperidone (Toridon) 10mg Dispersible Tablet is a white to off white, round, flat tablet with bisecting line on one side with fruity flavour.
PHARMACOLOGICAL PROPERTIES
Pharmacodynamics
Domperidone is a dopamine antagonist with antiemetic 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 antiemetic 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.
Pharmacokinetics
Absorption
The systemic bioavailability of domperidone is only about 15% in fasting subjects given a dose by mouth, although this is increased when domperidone is given after food. Patients with gastro-intestinal complaints should take Domperidone 15-30 minutes before a meal. Reduced gastric acidity impairs the absorption of Domperidone base. Oral bioavailability of Domperidone base is decreased by prior concomitant administration of cimetidine and sodium bicarbonate. The low bioavailability is thought to be due to first -pass hepatic and intestinal metabolism. The bioavailability of rectal domperidone is similar to that following oral administration, although peak plasma concentrations are only achieved after about an hour, compared with 30 minutes after a dose by mouth.
Distribution
Domperidone is more than (90%) bound to plasma protein. It does not readily cross the blood-brain barrier. Small amounts of domperidone are distributed into breast milk, reaching concentrations about one-quarter of those in maternal serum.
Metabolism
Domperidone undergoes rapid and extensive hepatic metabolism. The main metabolic pathways are N-dealkylation and by cytochrome P450 isoenzyme CYP3A4, and aromatic hydroxylation by CYP3A4, CYP1A2, and, CYP2E1.
Excretion
About 30% of an oral dose is excreted in urine within 24 hours, almost entirely as metabolites; the remainder of a dose is excreted in feces over several days, about 10% as unchanged drug. It has a terminal elimination half-life of about 7.5 hours.
INDICATIONS
- Indicated in various types of dyspepsia: delayed gastric emptying, GERD and esophagitis
- used for nausea and vomiting of various origins
- for the treatment of nausea and vomiting induced by radio or drug therapy

DOSAGE AND ADMINISTRATION
DIRECTION FOR USE:
Disperse the tablet in a teaspoonful of water before administration. And should be taken 15-30 minutes before meals.
For Nausea and vomiting – Adults and Adolescents ≥ 12 years weighing ≥ 35 Kg - It is administered in doses of 10 to 20 mg by mouth three or four times daily up to a maximum daily dose of 80 mg. Maximum treatment duration should not exceed one week. If nausea and vomiting persists for longer than one week, patients should consult their physician.
For Dyspepsia – Adult dose is usually 10mg up to 4 times daily (last dose to be taken at night); the dose may be increased to 20mg if necessary. A course treatment should not normally exceed 2 to 4 weeks.
Or as prescribed by the physician.
CONTRAINDICATIONS
- Domperidone is contraindicated in patients with known hypersensitivity to domperidone or any of the excipients
- Prolactin releasing pituitary tumor (prolactinoma)
- Patients with moderate or severe hepatic impairment
- Gastro Intestinal hemorrhage, obstruction, perforation or conditions where gastric motility could be harmful.
- Co-administration with potent CYP3A4 inhibitors which have been shown to cause QT interval prolongation.

WARNINGS AND PRECAUTIONS
Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. The risk may be more likely in those over 60 years old or in those taking doses higher than 30 mg per day. Therefore, domperidone should be used with caution in older patients. Patients older than 60 years of age should consult their physician before taking domperidone.
Due to increased risk of ventricular arrhythmia, domperidone is not recommended in patients with known existing prolongtation of cardiac conduction intervals, particularly QTc. In patients with significant electrolyte disturbances or bradycardia or in patients with underlying cardia diseases such as cardiac heart failure.
Domperidone is metabolized via cytochrome P450 isoenzyme CYP3A4. That concomitant use of drugs that is significantly inhibit the enzyme may result in increased plasma levels of domperidone. Co-administration of domperidone with potent CYP3A4 inhibitors which have been shown to cause QT interval prolongation should be avoided.
Domperidone is not recommended for chronic use or for the routine prophylaxis of postoperative nausea and vomiting.
PREGNANCY AND LACTATION
Domperidone should only be used during pregnancy when justified by the anticipated therapeutic benefit.
The amount of domperidone that could be ingested by an infant through breast milk is low. It is not known whether this is harmful to the newborn. Therefore, breast-feeding is not recommended for women who are taking domperidone.
DRUG INTERACTIONS
As with other dopamine antagonists, there is a theoretical potential that domperidone may antagonize the hypoprolactinaemic effect of drugs such as bromocriptine. In addition, the prokinetic effects of domperidone may alter the absorption of some drugs. Opioid analgesics and antimuscarinics may antagonise the prokinetic effects of domperidone.
Domperidone is metabolized via the cytochrome P450 isoenzyme CYP3A4; use with ketoconazole has been reported to produce a threefold increase in plasma concentrations of domperidone, and an associated slight prolongation in QT interval. Similar increases in domperidone concentrations might theoretically be seen with other potent inhibitors of CYP3A4 such as erythromycin or ritonavir, and such combinations may be best avoided. Caution should be exercised when domperidone is co-administered with potent CYP3A4 inhibitors which have not been shown to cause QT interval prolongation or drugs which have been shown to cause QT prolongation.
Antacids and antisecretory agents may also lower bioavailability of Domperidone.
ADVERSE REACTIONS
Plasma-prolactin concentrations may be increased, which may lead to galactorrhea or gynecomastia, amenorrhea, breast tenderness, breast pain, irregular menstruation, and lactation disorder. There have been reports of reduced libido, and rashes and other allergic reactions. Domperidone does not readily cross the blood-brain barrier and the incidence of central effects such as extrapyramidal reactions or drowsiness may be lower than with metoclopramide; however, there have been reports of dystonic reactions.
There have also been reports of depression, anxiety, headache, somnolence, akathisia, diarrhea, skin disorders like pruritus.
"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph or to TORRENT: www.torrentpharma.com".
Patient to seek medical attention immediately at the first sign of any adverse drug reaction shall appear.
OVERDOSAGE AND TREATMENT
Overdosage: Symptoms of overdosage may include agitation, altered consciousness, convulsions, disorientation, somnolence and extrapyramidal reactions.
Treatment: There is no specific antidote to domperidone, but in the event of overdose, gastric lavage within one hour of ingestion as well as the administration of activated charcoal may be useful. Close medical supervision and supportive therapy is recommended. Anticholinergic or anti-Parkinson drugs may be helpful in controlling extrapyramidal reactions.
STORAGE AND CONDITION
Store at temperatures not exceeding 30°C. Protect from light.
CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
AVAILABILITY
Domperidone (Toridon) 10 mg Dispersible Tablet - Foil Strip of 10's (Box of 100's) - DRP-2682
DATE OF FIRST AUTHORIZATION
August 18, 2003
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torrent PHARMA

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