

# DOMPERIDONE

xxxxxxx-5343

## TORIDON 1 mg/mL Suspension Prokinetic

### FORMULATION :

Each mL contains:

Domperidone ..... 1 mg

### PHARMACOKINETICS :

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. 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.

Domperidone is more than (90%) bound to plasma protein, and has a terminal elimination half-life of about 7.5 hours. It is chiefly cleared from the blood by extensive metabolism. 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 faeces over several days, about 10% as unchanged drug. 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.

### INDICATIONS :

It is used as an antiemetic for short-term treatment of nausea and vomiting of various aetiologies, including that associated with cancer therapy, and nausea and vomiting associated with levodopa or bromocriptine therapy for parkinsonism. It is not considered suitable for chronic nausea and vomiting, nor for the routine prophylaxis of postoperative vomiting.

Domperidone is also used for its prokinetic actions in disorders of gastro-intestinal motility such as diabetic gastroparesis and has been tried in other gastro-intestinal disorders.

### DRUG INTERACTIONS :

The effects of CNS depressants may also be enhanced by antimuscarinic agents and opioids analgesics antagonize the gastro-intestinal effects of domperidone. The absorption of other drugs may be affected by domperidone; it may either diminish absorption from the stomach or enhance absorption from the small intestine. It may prolong

suxamethonium-induced neuromuscular blockade. Domperidone may also increase prolactin blood-concentrations and therefore interfere with drugs which have a hypoprolactinaemic effect.

### DOSAGE AND ADMINISTRATION :

For Nausea and vomiting - In children doses of 250 to 500 mcg/kg body weight 3 to 4 times daily up to maximum daily dose of 2.4 mg/kg and should not exceed a total of 80 mg daily.

### ADVERSE EFFECTS :

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. Plasma-prolactin concentrations may also be increased which may lead to galactorrhoea or gynaecomastia.

### PRECAUTIONS :

Domperidone should not be used when stimulation of muscular contractions might adversely affect gastro-intestinal conditions as in gastro-intestinal hemorrhage, obstruction, perforation, or immediately after surgery. Care should also be taken to patients with renal impairment or to those at risk of fluid retention as hepatic impairment, and also in patients taking other drugs that can also cause extrapyramidal reactions, such as the phenothiazines.

### STORAGE :

Store at a temperatures not exceeding 30°C. Protect from light.

Shake well before using.

### CAUTION :

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

### AVAILABILITY :

Domperidone (Toridon) 1 mg/mL Suspension - Amber glass bottle of aluminum ROP cap x 30 mL and rubber dropper-1 box of 1's



Manufactured For:

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TORIDON