DOMPERIDONE

APULDON

5 mg/ mL Suspension (Oral Drops)

5 mg / 5 mL (1 mg/mL) Suspension

Gastrokinetic (Prokinetic) ℞

FORMULATION:

Suspension (Oral Drops)

Each mL contains:

Domperidone ..... 5 mg.

Suspension:

Each 5 mL contains:

Domperidone ..... 5 mg.

PRODUCT DESCRIPTION:

Drops: A yellow colored homogeneous suspension having sweet taste and mixed flavor of Lemon and Banana, free from any visible foreign particles.

Suspension: A yellow colored homogeneous suspension having sweet taste and mixed flavor of Lemon and Banana.

PHARMACOKINETICS:

Although absorption is rapid, the systemic bioavailability of domperidone is only about 15% in fasting subjects given an oral dose; 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 after oral doses, although peak plasma concentrations are only about one-third that of an oral dose and are achieved after about an hour, compared with 30 minutes after an oral dose.

Domperidone is more than 90% bound to plasma proteins, and has a terminal elimination half-life of about 7.5 hours. It undergoes rapid and extensive hepatic metabolism. The main metabolic pathways are N-dealkylation by cytochrome P450 isoenzyme CYP3A4, and aromatic hydroxylation by CYP3A4, CYP1A2, and CYP2E1. About 30% of an oral dose is excreted in urine 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 breastmilk; concentrations are 10 to 50% of those in maternal serum.

INDICATION(S):

It is used as an antiemetic for the short-term treatment of nausea and vomiting of various etiologies. Also used for its prokinetic actions in dyspepsia.

DOSAGE AND ADMINISTRATION:

Adults and adolescents (12 years of age and older and weighing 35 kg or more): 10 mL (of oral suspension containing domperidone 5mg per 5mL) up to three times per day with a maximum daily dose of 30 mL per day.

Neonates, infants, children (less than 12 years of age) and adolescents weighing less than 35 kg: The dose is 0.25 mg/kg. This should be given up to three times per day with a maximum dose of 0.75 mg/kg per day. For example, for a child weighing 10 kg, the dose is 2.5 mg and this can be given three times per day to a maximum dose of 7.5 mg per day.

Or as prescribed by the physician.

Oral domperidone should be taken before meals/feeding. If taken after meals absorption of the drug is somewhat delayed.

Hepatic Impairment: Domperidone is contraindicated in moderate or severe hepatic impairment. Dose modification in mild hepatic impairment is however not needed.

Renal Impairment: Since the elimination half-life of domperidone is prolonged in severe renal impairment, on 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.

Shake the bottle well before use.

ADVERSE EFFECTS:
Plasma prolactin concentrations may be increased, which may lead to galactorrhoea or gynaecomastia. 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.
Domperidone by injection has been associated with convulsions, arrhythmias, and cardiac arrest. Fatalities have restricted use by this route.

PRECAUTIONS:
Domperidone is not recommended for chronic use or for the routine prophylaxis of postoperative nausea and vomiting. Domperidone should be used with great caution if given intravenously, because of the risk of arrhythmias, especially in patients predisposed to cardiac arrhythmias or hypokalaemia.

REPORTING OF SUSPECTED ADVERSE REACTIONS:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions, directly to the importer/distributor and/or to FDA: www.fda.gov.ph. Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

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 antimuscarinic may antagonize the prokinetic effects of domperidone.
Domepridone 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 best avoided.

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

STORAGE CONDITION:
Store at temperature not exceeding 30^0C.

AVAILABILITY:
Suspension (Oral Drops): Amber Bottle with plastic dropper x 15 mL (Box of 1's).
FDA Registration No. : DR-XY41660
Date of Renewal of Authorization : 05 March 2020

Suspension: Amber Bottle 60 mL (Box of 1's).
FDA Registration No. : DRP-7422
Date of Renewal of Authorization : 01 December 2020
Date of Revision of package insert : 18 January 2022

Manufactured by:
ARISTOPHARMA LTD.
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