

DOMIDONE CHAPHA®

Active ingredient:

Domperidone 1mg/mL.

Excipients:

Polysorbate, Avicel, Tylose, sorbitol, methyl paraben, propyl paraben, sucralose and purified water.

PHARMACEUTICAL FORM

Oral suspension. 200mL bottle.

PHARMACOTHERAPEUTIC CLASS

Antiemetic; Dopamine Antagonist;

Gastroprokinetic agent.

PHARMACOLOGICAL PROPERTIES

Domperidone is a dopamine antagonist with antiemetic properties. Domperidone does not readily cross the blood-brain barrier. But it causes a rise in prolactin levels from the pituitary. Animal studies indicate a predominantly peripheral effect of domperidone on dopamine receptors.

Domperidone increases esophageal peristalsis and increases lower esophageal sphincter pressure, increases gastric motility and peristalsis, and enhances gastroduodenal coordination. therefore, facilitating gastric emptying and decreasing small bowel transit time.

Domperidone has no effect on gastric secretion.

PHARMACOKINETICS

Domperidone is rapidly absorbed following oral administration with peak plasma concentrations achieved at approximately 30 to 60 minutes.

Domperidone is highly bound (91-93%) to plasma proteins. Oral domperidone does not appear to accumulate or to induce its own metabolism.

Domperidone undergoes rapid and extensive hepatic metabolism via N-dealkylation (CYP 3A4) and aromatic hydroxylation (CYP 3A4, and CYP 1A2).

Domperidone is excreted in feces (66%) and in urine (31%). The proportion of the drug excreted unchanged is small (10% of faecal excretion and approximately 1% of urinary excretion).

The plasma half-life after a single oral dose is approximately 7-9 hours.

INDICATIONS

Domidone Chapha® is indicated for:

1. The dyspeptic symptom complex that is often associated with delayed gastric emptying, gastroesophageal reflux and oesophagitis:

- epigastric sense of fullness, early satiety, feeling of abdominal distension, upper abdominal pain;

- bloating, eructation, flatulence;
- nausea and vomiting;
- heartburn with or without regurgitations of gastric contents in the mouth.

2. Nausea and vomiting of functional, organic, infectious or dietetic origin or induced by radiotherapy or drug therapy.

ADVERSE REACTIONS

Occasionally, dry mouth, transient skin rash or itching, headache, thirst, diarrhea and

nervousness may occur.

Domperidone may induce an increase in the plasma prolactin level leading, in rare cases, to galactorrhoea and gynaecomastia.

OVERDOSAGE

Symptoms of overdose include CNS effects (drowsiness, disorientation, and extrapyramidal reactions) and cardiovascular effects (arrhythmias and hypotension).

Treatment is supportive. The administration of activated charcoal, and close observation of the patient are recommended.

DRUG INTERACTIONS

Please inform your doctor if other medicines are being taken concomitantly with Domidone Chapha®.

PRECAUTIONS

Domidone Chapha® should be avoided in children younger than 1 year of age, because the blood-brain barrier is immature, hence CNS symptoms may eventually occur.

Use with caution in patients with hepatic impairment.

Use under medical supervision in patients who have existing prolongation of cardiac conduction intervals (particularly QTc), significant electrolyte disturbances or underlying cardiac disease (e.g., congestive heart failure); particularly in patients older than 60 years and patients who receive daily oral doses of more than 30mg.

CONTRA - INDICATIONS

Hypersensitivity to domperidone or any component of the formulation;

Patients with gastrointestinal haemorrhage, mechanical obstruction, or perforation;

Patients with prolactin-releasing pituitary tumor (prolactinoma).

Coadministration with CYP 3A4 inhibitors which prolong the QTc interval.

DOSAGE AND ADMINISTRATION

Domidone Chapha® should be taken 15 to 30 minutes before meal. Domperidone should be used at the lowest effective dose.

Children: 2.5mL per 10 kg body weight;

Adults: 10mL.

The dose should be taken 3 times daily before meals.

Shake well before use.

CONSERVATION

All medicines should be kept out of children's reach.

Do not use when expired (expiry date on the box).

Keep at room temperature under 30°C, and protect from light.



Manufactured by CHAPHA

(Chalhoub Pharmaceuticals) S.A.L.

Made in Lebanon.