FARCOTILIUM
Capsules, Oral Suspension & Adult Suppositories

Gastroprokinetic and Antiemetic

Composition:

Each formulation contains:	Capsule	Oral Susp.	Supp.
Domperidone	10 mg	5 mg/5 ml	60 mg

Properties:

FARCOTILIUM (domperidone) is an effective antiemetic and Gastroprokinetic agent for treatment of nausea, vomiting and other dyspeptic symptoms associated with delayed gastric emptying and gastroesophageal reflux. **FARCOTILIUM** is a selective peripheral dopamine antagonist at the D_2 receptors. It stimulates upper GI motility, increases the lower esophageal sphincter pressure, promotes esophageal and antral contractions, relaxes pyloric sphincter and increases duodenal and jejunal peristalsis. The overall effect of **FARCOTILIUM** is prevention of gastroesophageal reflux, acceleration of gastric emptying and reduction of the transit time of intestinal contents from the duodenum to ileocecal valve. Clinically, **FARCOTILIUM** therapy corrects disturbances of GI motility with prompt relief of associated eructation, flatulence, heartburn and abdominal discomfort. **FARCOTILIUM** has no effect on GI secretions or colonic motility and does not cause diarrhea. Also, **FARCOTILIUM** does not cross the blood-brain barrier, so its use in the treatment of nausea and vomiting does not cause the psycholtropic or neurologic adverse effects commonly encountered with the currently available antiemetics. **FARCOTILIUM** is available in three dosage forms (Capsules, Oral Suspension and Adult Suppositories) to suit patients of all age groups under different conditions.

Pharmacokinetics:

Following **FARCOTILIUM** administration, domperidone is rapidly absorbed from the GIT. Presystemic metabolism occurs in the gut wall and liver. Peak plasma concentrations are achieved within 30 minutes of oral administration and after about one hour following rectal administration. Domperidone is distributed into most body tissues and fluids but does not cross the blood-brain barrier. More than 90 % of the drug is bound to plasma proteins. It is chiefly cleared from the body by extensive metabolism in the liver and the resulting metabolites are excreted in the urine and feces. The plasma elimination half life of the drug is about 7.5 hours.

Indications :

- Prevention and treatment of nausea and vomiting associated with :
- Cytotoxic chemotherapy and radiotherapy.
- Levodopa and bromocriptine administration as in parkinsonism.
- Gastritis, hepatitis and pancreatitis.
- Severe migraine.
- Dysmenorrhea.
- Prior to GI radiography and endoscopy.
- Correction of gastrointestinal motility disorders as in :
- Non-ulcer dyspepsia associated with eructation, flatulence, heartburn and abdominal distension and discomfort.
- Gastroesophageal reflux.
- Gastrointestinal paresis associated with diabetes mellitus and neurologic diseases.
- Postoperative nausea and vomiting.

Dosage :

The capsules and oral suspension should be given 15 - 30 minutes before meals and at bedtime if required.

Adults :

Capsules : 1-2 capsules (10 - 20 mg), 3 - 4 times daily.
Suspension : 2-4 teaspoonfuls (10 - 20 ml), 3 - 4 times daily.
Suppositories : one suppository every 8 hours.

Children :

0.2 - 0.4 mg/kg body weight every 4 - 8 hours.

Contraindications:

Hypersensitivity to domperidone.

Precautions:

Domperidone should be used with caution in renal impairment.

Side effects:

FARCOTILIUM is safe and well tolerated. However, dry mouth, headache, facial flushing and increased serum prolactin levels may occur.

Pregnancy and lactation :

Although animal studies did not demonstrate any teratogenic effect on the fetus, domperidone should be used during pregnancy under medical supervision. Domperidone may improve postnatal lactation and its secretion in breast milk is very small and insufficient to cause harm to the baby.

Drug interactions:

Domperidone antagonizes the hyperprolactinemic effect of bromocriptine. The effect of domperidone on GI motility may be antagonized by antimuscarinics and opioid analgesics. Domperidone may enhance the absorption of concomitantly administered drugs particularly in patients with delayed gastric emptying.

Interference with laboratory tests :

None reported.

Overdosage and treatment :

Accidental ingestion of very high doses may cause gastrointestinal disturbances and extrapyramidal effects. Treatment includes gastric lavage and symptomatic treatment.

Packing:

A box containing 24 capsules or 5 adult suppositories.
A bottle containing 120 ml or 200 ml suspension.

Storage

Keep at temperature (15 - 30° C).
The capsules and suppositories should be kept away from moisture.
Keep out of the reach of children.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.

Made in Egypt

PHARCO Pharmaceuticals
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