

Only for the use of Medical Professionals

Vave®

Domperidone

Description

Vave® is a dopamine antagonist that principally blocks the dopamine receptors located in the chemoreceptor trigger zone (CTZ) and stomach. Its gastro-prokinetic action is based on its blocking effect of dopamine receptors that have an influence on the motility of gastro-intestinal tract. Due to its weak penetration across the blood-brain barrier, **Vave®** has almost no effect on the dopaminergic receptors in the brain therefore excluding psychotropic and neurologic side effects. **Vave®** restores normal motility and tone of the upper gastro-intestinal tract, facilitates gastric emptying, enhances antral and duodenal peristalsis and regulates contraction of the pylorus. **Vave®** also increases esophageal peristalsis and lower esophageal sphincter pressure, and thus prevents regurgitation of gastric content.

Indications

Vave® is indicated for

- Stimulation of gut mobility
 - a) non-ulcer dyspepsia
 - b) esophageal reflux, reflux esophagitis and gastritis
 - c) diabetic gastroparesis
 - d) functional dyspepsia
 - e) speeding barium transit in "follow through" radiological studies
- Prevention and symptomatic relief of acute nausea and vomiting in adults from any cause including cytotoxic therapy, radio therapy and anti-parkinsonism therapy.
- In the treatment of nausea associated with migraine attack.

Dosage and administration

Dose and frequency of administration should be adjusted according to severity and duration of symptoms. **Vave®** tablet, ODT, suspension and paediatric drops should be taken 15-30 minutes before meal.

For the treatment of nausea and vomiting:

Adults: 10-20 mg (1-2 **Vave®** tablet/ **Vave®** ODT or 10-20 ml suspension), every 4-8 hours daily.

Children: 0.2-0.4 mg/kg (0.2-0.4 ml suspension/kg or 0.04-0.08 ml paediatric drops/kg) body weight, every 4-8 hours daily.

A course of treatment should not exceed 12 weeks.

For the treatment of symptoms of functional dyspepsia:

Adults: 10-20 mg (1-2 **Vave®** tablet/ **Vave®** ODT or 10-20 ml suspension), every 4-8 hours daily.

Children: 0.2-0.4 mg/kg (0.2-0.4 ml suspension/kg or 0.04-0.08 ml paediatric drops/kg) body weight, every 4-8 hours daily.

Use in pregnancy and lactation

Pregnant women: Safe use in pregnant women has not been established and therefore it is not recommended during pregnancy, although studies in animals have not demonstrated teratogenic effects. Lactating mother: Domperidone may precipitate galactorrhea and improve postnatal lactation. It is secreted in breast milk but on very small quantities, insufficient to be considered harmful.

Contraindications

Domperidone is contraindicated to the patients with known hypersensitivity to this drug and in case of neonates.

Precautions

Domperidone should be used with absolute caution in case of children because there may be increased risk of extra-pyramidal reactions in young children because of an incompletely developed blood-brain barrier. Since Domperidone is highly metabolized in liver, it should be used with caution in patient with hepatic impairment.

Side effects

The common side effect of Domperidone is hyperprolactinemia which may result in galactorrhea, breast enlargement, soreness and reduced libido. Other side effects are dry mouth, thirst, headache, nervousness, drowsiness, diarrhea, skin rash and itching which may occur during treatment with Domperidone. Extra-pyramidal reactions are seen in 0.05% of patients in clinical studies.

Drug Interactions

Domperidone may reduce the hypoprolactinemic effect of bromocriptine. The actions of Domperidone on gastro-intestinal function may be antagonized by antimuscarinics and opioid analgesics.

Overdose

No case of overdosage with oral domperidone has been reported. There is no specific antidote to Domperidone but in the event of overdosage gastric lavage may be useful.

Pharmaceutical precautions

Store in a cool dry place. Protect from light.

Presentation

Vave® 10 mg Tablets: Each coated tablet contains Domperidone 10 mg as Maleate BP.

Vave® ODT 10 mg: Each orodispersible tablet contains Domperidone BP 10 mg.

Vave® Suspension: Each 5 ml contains Domperidone BP 5 mg.

Vave® 15 ml Paediatric Drops: Each ml contains Domperidone BP 5 mg.

Package quantities

Vave® 10 mg Tablets: Carton of 150 tablets in blister.

Vave® 10 mg Tablets: Carton of 100 tablets in blister (For Export only).

Vave® ODT 10 mg: Carton of 100 tablets in blister.

Vave® Suspension: Bottle of 100 ml and 60 ml.

Vave® 15 ml Paediatric Drops: Bottle of 15 ml.

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