

# Motigut<sup>®</sup>

## Domperidone

### COMPOSITION

**Motigut<sup>®</sup>** Tablet: Each tablet contains Domperidone 10 mg (as Domperidone Maleate EP).

**Motigut<sup>®</sup>** Suspension: Each 5 ml suspension contains Domperidone EP 5 mg.

**Motigut<sup>®</sup>** Paediatric Drops: Each ml contains Domperidone EP 5 mg.

### PHARMACOLOGY

**Motigut<sup>®</sup>** is a dopamine antagonist that principally blocks the dopamine receptors located in the Chemoreceptor Trigger Zone (CTZ) and stomach. Its gastroprokinetic 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, **Motigut<sup>®</sup>** has almost no effect on the dopaminergic receptors in the brain therefore excluding psychotropic and neurologic side effects.

**Motigut<sup>®</sup>** 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. **Motigut<sup>®</sup>** also increases esophageal peristalsis and lower esophageal sphincter pressure, and thus prevents regurgitation of gastric content.

### INDICATION

- Dyspeptic symptom complex**, often associated with delayed gastric emptying, gastro-esophageal reflux and esophagitis:
  - Epigastric sense of fullness, feeling of abdominal distension, upper abdominal pain
  - Ercutation, flatulence, early satiety
  - Nausea and vomiting
  - Heartburn with or without regurgitations of gastric contents in the mouth
  - Non-ulcer dyspepsia
- Acute nausea and vomiting** of functional, organic, infectious, dietetic origin or induced by radiotherapy or drug therapy or induced in migraine.
- Parkinson's disease**: In dopamine-agonist induced nausea and vomiting.
- Radiological studies**: Speeding barium transit in follow-through radiological studies.

### DOSAGE AND ADMINISTRATION

**Motigut<sup>®</sup>** should be taken 15-30 minutes before meals and, if necessary, before retiring.

The usual recommended oral dose of Domperidone is as follows:

**Adults**: 10-20 mg (1-2 **Motigut<sup>®</sup>** tablet or 10-20 ml **Motigut<sup>®</sup>** suspension), every 6-8 hours daily. Maximum dose of Domperidone is 80 mg daily.

**Children**: 2-4 ml **Motigut<sup>®</sup>** suspension/10 Kg body weight or 0.4-0.8 ml **Motigut<sup>®</sup>** Paediatric Drops/10 Kg body weight, every 6-8 hours daily.

**In dyspeptic symptom**: The recommended oral dose for **Adults**: 10-20 mg (1-2 **Motigut<sup>®</sup>** tablet or 10-20 ml **Motigut<sup>®</sup>** suspension), every 6-8 hours daily. **Children**: 0.2-0.4 mg/Kg (2-4 ml) **Motigut<sup>®</sup>** suspension/10 Kg or 0.4-0.8 ml, **Motigut<sup>®</sup>** Paediatric Drops/10 Kg) body weight, every 6-8 hours daily.

**In acute and sub-acute conditions (mainly in acute nausea and vomiting)**:

The recommended oral dose for-

**Adults**: 20 mg (2 **Motigut<sup>®</sup>** tablet or 20 ml **Motigut<sup>®</sup>** suspension), every 6-8 hours daily

**Children**: 0.2-0.4 mg/Kg (2-4 ml **Motigut<sup>®</sup>** suspension/10 Kg or 0.4-0.8 ml **Motigut<sup>®</sup>** Paediatric Drops 10 Kg) body weight, every 6-8 hours daily.

(In acute nausea and vomiting maximum period of treatment is 12 weeks).

### SIDE EFFECTS

Domperidone may produce hyperprolactinemia (1.3%). This may result in galactorrhea, breast enlargement, and soreness and reduced libido. Dry mouth (1%), thirst, headache (1.2%), nervousness, drowsiness (0.4%), diarrhea (0.2%), skin rash and itching (0.1%) may occur during treatment with domperidone. Extra-pyramidal reactions are seen in 0.05% of patients in clinical studies.

### PRECAUTION

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.

### USE IN PREGNANCY AND LACTATION

**Pregnant women**: The safety of domperidone has not been proven and it is therefore not recommended during pregnancy. Animal studies have not demonstrated teratogenic effect in the fetus. **Lactating mother**: Domperidone may precipitate galactorrhea and improve post-natal lactation. It is secreted in breast milk but in very small quantities insufficient to be considered harmful.

### CONTRAINDICATION

Domperidone is contraindicated to patients having known hypersensitivity to this drug and in case of neonates. Domperidone should not be used whenever gastro-intestinal stimulation might be dangerous i.e., gastro-intestinal hemorrhage, mechanical obstruction or perforation. Also contraindicated in patients with prolactin releasing pituitary tumor (prolactinoma).

### DRUG INTERACTION

Domperidone may reduce the risk of hypoprolactemic effect of bromocriptine. The action of Domperidone on GI function may be antagonized by anti-muscarinics and opioid analgesics. Care should be exercised when domperidone is administered in combination with MAO (monoamine oxidase) inhibitors

### OVERDOSE

There are no reported cases of overdose.

### STORAGE CONDITION

Store below 30°C, Protected from light & moisture. Keep out of children's reach.

### HOW SUPPLIED

**Motigut<sup>®</sup>** Tablet: Box containing 100 tablets in blister pack.

**Motigut<sup>®</sup>** Suspension: Bottle containing 60 ml Suspension.

**Motigut<sup>®</sup>** Paediatric Drops: Bottle containing 15 ml drops.

Manufactured by



**SQUARE**  
PHARMACEUTICALS LTD.  
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