Dosage and Administration:
The recommended oral dose for
Adults: 10-20mg every 4-8 hours daily.
Children: 0.2-0.4 mg/kg body weight every 4-8 hours daily.
Motinorm (Domperidone) should be taken 15-30 minutes before a meal. For acute vomiting and nausea, maximum period of treatment is 12 weeks. Use in children is restricted to nausea and vomiting following cytotoxics or radiotherapy.

Use in patients with impaired hepatic function:
Motinorm (Domperidone) is highly metabolized in the liver, should be used with caution in patients with hepatic impairment.

Use in patients with impaired renal function:
It is unlikely that the dose needs to be adjusted for single administration in patients with renal insufficiency. However, on repeated administration the dosing frequency will need to be reduced to once or twice daily depending on the severity of the impairment. The dose may also need to be reduced. Generally, patients on prolonged therapy should be reviewed regularly.

Side Effects:
Motinorm (Domperidone) may produce hyperprolactinemia (1.3%). This may result in galactorrhea, breast enlargement and soreness and reduced libido.

Contraindications:
Motinorm (Domperidone) is contraindicated to patients having known hypersensitivity to this drug and in case of neonates. It is also contraindicated in patients with prolactin releasing pituitary tumor (prolactinoma).

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: Motinorm (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.

Precautions :
Motinorm (Domperidone) should be used with 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.

Drug Interactions :
Motinorm (Domperidone) may antagonise the hypoprolactinaemic effect of drugs such as bromocriptine. In addition, Opioid analgesics and antimuscarinics may antagonise the prokinetic effects of domperidone.

PHARMACEUTICAL INFORMATION:
Storage Conditions:
Store in a cool and dry place and protect from light. Keep out of the reach of children.
Presentation:
Motinorm Tablet: Each commercial box contains 10 X 10 tablets in Alu-PVC blister pack.

Manufactured by:

Sharif Pharmaceuticals Ltd.
Rupganj, Narayanganj, Bangladesh.

P12005

SHARIF
Pharmaceuticals Ltd.

Motinorm
Domperidone

COMPOSITION:
Motinorm Tablet: Each film coated tablet contains Domperidone Maleate BP equivalent to 10mg of Domperidone.

PHARMACOLOGICAL INFORMATION:
Pharmacological Action:
Motinorm (Domperidone) is a peripheral dopamine D_2 - receptor antagonist with gastroprokinetic and anti-emetic properties. It is used in the treatment of symptoms of nausea and vomiting of variable origin. Motinorm effectively increases esophageal peristalsis and lower esophageal sphincter pressure (LESP), increases gastric motility and peristalsis, enhances gastroduodenal coordination and consequently facilitates gastric emptying and decreases small bowel transit time.

Mechanism of Action:
The gastroprokinetic properties of domperidone are related to its peripheral dopamine receptor blocking properties. Domperidone facilitates gastric emptying and decreases small bowel transit time by increasing esophageal and gastric peristalsis. The antiemetic properties of domperidone are related to its dopamine receptor blocking activity at both the chemoreceptor trigger zone and at the gastric level.

Pharmacokinetics:
The systemic bioavailability of domperidone is only about 15% in fasting subjects given a dose by mouth, although this is increased when domperidone is given after food. The low bioavailability is thought to be due to first-pass hepatic and intestinal metabolism.
Domperidone is more than 90% bound to plasma proteins and has a terminal elimination half-life of about 7.5 hours. It is chiefly cleared from the blood by extensive metabolism. About 30% of an oral dose is excreted in urine within 24 hours, almost entirely as metabolites; the remainder of a dose is excreted in feces over several days, about 10% as unchanged drug. It does not readily cross the blood-brain barrier.
Small amount of domperidone are distributed into breast milk, reaching concentrations about one-quarter of those in maternal serum.

CLINICAL INFORMATION:
Therapeutic Indications:
- Prevention and symptomatic relief of acute nausea and vomiting from any cause
- Non-ulcer dyspepsia
- Functional dyspepsia
- Diabetic gastroparesis
- Heartburn
- Epigastric sense of fullness, feeling of abdominal distension, upper abdominal pain
- Gastro-esophageal reflux diseases
- Stimulation of gut motility
- Relieves nausea associated with migraine attack