

Composition

Fixgut Tablet: Each film coated tablet contains Domperidone maleate BP equivalent to 10 mg Domperidone.

Fixgut Suspension: Each 5 ml suspension contains Domperidone BP 5 mg.

Pharmacology

Domperidone is a selective peripheral dopamine D2 receptor antagonist. Principally it acts in the chemoreceptor trigger zone (CTZ) and stomach.

Indications

Prevention & symptomatic relief of acute nausea and vomiting of adults (from any cause specially due to cytotoxic therapy & radiotherapy). Nausea & vomiting associated with L-dopa and bromocriptine treatment for parkinsonian patients. Nausea & vomiting due to migraine, head injury, pancreatitis, gastritis, hepatitis, post-gastrectomy syndrome, haemodialysis and dysmenorrhoea. Non ulcer dyspepsia, oesophageal reflux, reflux oesophagitis & gastritis. Speeding of barium transit in 'follow through' radiological studies.

Dosage & Administration

Adult & Elderly patients: 10-20 mg every 4-8 hours. Domperidone should be taken 15-30 minutes before meal or as directed by the physician.

Contraindications

Domperidone is contraindicated in patients with known allergy or hypersensitivity, prolactinoma and in pregnancy. It should be used cautiously in children unless indicated for the management of nausea and vomiting following cancer chemotherapy or irradiation therapy.

Precautions

The drug is not recommended for use in neonates. Domperidone may precipitate galactorrhoea & improve post-natal lactation.

Side Effects

Domperidone increases level of serum prolactin which may be associated with galactorrhoea & gynaecomastia. Occasionally, rash and other allergic phenomena have been reported. Besides dry mouth, thirst, headache, diarrhoea, skin rash and reduced libido may follow treatment with domperidone.

Use in Pregnancy & Lactation

Domperidone should not be used in pregnant women unless the expected benefit outweighs any potential risk. Domperidone is excreted in breast milk in very low concentration. Hence, it is not recommended in lactating mothers.

Use in Children & Adolescents

The safety and efficacy of Domperidone in children have not been established. So, Domperidone should not be used in children.

Drug Interactions

Domperidone may reduce the hypoprolactinaemic effect of bromocriptine. Antacids and anti-secretory agents lower the oral bioavailability of domperidone, so they should be taken after meals and not with domperidone simultaneously.

Overdosage

Overdose has been reported primarily in infants and children. Symptoms of overdose may include agitation, altered consciousness, convulsion, disorientation, somnolence and extrapyramidal reactions. There is no specific antidote to domperidone. Anticholinergic agents may be helpful in controlling the extrapyramidal reactions. Close observation and supportive therapy is recommended.

Storage

Keep away from light & moisture and store below 30° C. Keep out of the reach of children.

Packing

Fixgut Tablet: Each box contains 10 X 10 tablets in Alu-PVC blister pack and an insert.

Fixgut Suspension: Each bottle contains 60 ml suspension.