

DOMPERIDONE TABLETS

Gastrium

COMPOSITION: Each tablet contains Domperidone BP 10mg.

CHEMISTRY: Domperidone is a benzimidazole derivative, the full chemical name being 5-chloro-1-[1-(3-(2-oxobenzimidazolin-1-yl)propyl)-4-piperidyl]benzimidazolin-2-one.

PHARMACOLOGICAL CATEGORY: Antiemetic and Prokinetic.

PHARMACOLOGY: Selective antagonism of peripheral dopamine D2 receptors in the stomach and the Chemoreceptor Trigger Zone, increases peristalsis in the upper GI tract and facilitates gastric emptying.

Pharmacokinetics : Domperidone is rapidly and completely absorbed from the gut. Given 90 minutes after food, absorption is delayed but bioavailability is higher. Strongly bound to plasma proteins (91-93%), not only to albumin but to lipoproteins as well. Metabolism takes place in gut wall and liver. Almost completely metabolised and excreted in urine and faeces. Half-life is 7.5 hours.

INDICATIONS AND USES :

1. Prevention and relief of nausea and vomiting due to a variety of causes especially:

Surgery, Cancer chemotherapy, Radiotherapy, Levodopa and bromocriptine therapy for parkinsonism, Migraine, hepatitis, pancreatitis, head injury, dysmenorrhoea.

2. Delayed gastric emptying and gastroparesis
3. Reflux oesophagitis
4. Dyspepsia.

CONTRAINDICATIONS: Domperidone is contraindicated in patients with known hypersensitivity to this drug.

SIDE EFFECTS/ADVERSE REACTIONS: Domperidone has been well tolerated in most studies. No side effects have been reported at doses of 30 and 60 mg daily for several weeks. Occasional minor side effects include dryness of mouth, thirst, headache, diarrhoea, nervousness and transient rash.

Extrapyramidal side effects have been rare and far less frequent with Domperidone than with metoclopramide.

Domperidone can stimulate prolactin secretion and may rarely cause galactorrhoea or gynaecomastia.

PRECAUTIONS & WARNINGS : Domperidone may cause extrapyramidal reactions especially in young adults and in the elderly. These may be treated with antiparkinson drugs.

DRUG INTERACTIONS: Domperidone may reduce the hypoproactinaemic effect of bromocriptine but not its antiparkinson effect.

USE IN PREGNANCY & LACTATION : It is preferable not to use this drug during pregnancy.

Nursing mothers: Domperidone is excreted into breast milk only in small amount with no potential for causing reactions in the child.

DOSAGE & ADMINISTRATION : Adults : 10 to 20 mg three or four times a day 15-30 minutes before meals. The fourth dose is given at bedtime.

Children : 0.2 to 0.3 mg/kg 3 or 4 times a day before feeding.

Elderly: No dosage changes are required in the elderly.

OVERDOSAGE, SYMPTOMS AND ANTIDOTE : There are no known reports of overdosage with Domperidone. If this happens gastric lavage, symptomatic and supportive measures should be adequate. Sedation and/or acute dystonic reactions may occur. The latter may be treated with antiparkinson drugs.

Food Interactions: Food reduces the first pass metabolism of Domperidone in the gut wall. Results are delayed absorption but increased bioavailability.

PRESENTATION : Blister pack of 10's

STORAGE: Store below 25°C, in a dry place. Protect from light.

DATE OF PUBLICATION: JANUARY 2001.

Manufactured by:
MICRO LABS LIMITED
92, SIPCOT, HOSUR-633 126, INDIA.

SIN 10198P
EXG-ML12I-1882