

1. NAME OF THE MEDICINAL PRODUCT

Domperidone 10mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Domperidone (as maleate) 10mg

For excipients see 6.1

3. PHARMACEUTICAL FORM

Tablet

White, round, biconvex tablet embossed DM10 on one side

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Adults (including the elderly):

1. For the acute treatment of nausea and vomiting of any aetiology, in adults. The drug is not recommended for chronic use or for the routine prophylaxis of postoperative vomiting.

2. For up to 12 weeks treatment of nausea and vomiting caused by L- dopa and bromocriptine

3. For the treatment of symptoms of functional dyspepsia.

Children: The drug is not recommended for use in children unless indicated for the management of nausea and vomiting following cancer chemotherapy or irradiation.

4.2. Posology and method of administration

Domperidone 10mg Tablets are for oral administration.

Dose, route and frequency of administration should be adjusted according to severity and duration of symptoms.

For the treatment of the nausea and vomiting:

Adults (including the elderly): 10-20 mg by mouth at 4-8 hourly intervals.

Children: Not appropriate for children, use suspension.

For the treatment of the symptoms of functional dyspepsia:

Adults (including the elderly): Up to 10-20 mg orally 3 times daily before meals and 10-20 mg at night depending on clinical response.

A course of treatment should not exceed 12 weeks.

Children: Not recommended

4.3. Contraindications

Domperidone 10 mg Tablets are contraindicated when stimulation of gastric motility might be dangerous (e.g. in patients with haemorrhage, mechanical obstruction or perforation) and in patients with prolactin-releasing pituitary tumour (prolactinoma)

4.4. Special warning and precautions for use

Domperidone 10mg Tablets are not recommended for chronic administration

4.5. Interaction with other medicinal products and other forms of interaction

Whilst adverse interactions have not been reported in general clinical use, it is clear that there is a theoretical potential for domperidone to interact with several classes of agent. Domperidone may, therefore, alter the peripheral actions of dopamine agonists such as bromocriptine, including its hypoprolactinaemic action. The actions of domperidone on gastrointestinal function may be antagonised by antimuscarinics and opioid analgesics. Domperidone may enhance the absorption of concomitantly administered drugs, particularly in patients with delayed gastric emptying.

4.6. Pregnancy and lactation

Safe use in pregnant woman has not been established, although studies in animals have not demonstrated teratogenic effects. It is therefore not advisable to administer domperidone in pregnancy. Domperidone is excreted in breast milk but at very low levels.

4.7. Effects on ability to drive and use machines

None

4.8. Undesirable effects

In common with other dopamine antagonists, domperidone produces a rise in serum prolactin which may be associated with galactorrhoea, and less frequently with gynaecomastia, breast enlargement or soreness, there have been reports of reduced libido.

Domperidone does not readily cross the normally functioning blood brain barrier and therefore is less likely to interfere with central dopaminergic function.

However, acute extrapyramidal dystonic reactions including rare instances of oculogyric crises, have been reported with domperidone.

Should treatment of a dystonic reaction be necessary, domperidone should be withdrawn and an anticholinergic anti-parkinson drug, or a benzodiazepine should be used.

Occasional rashes and other allergic phenomena, including rare cases of anaphylaxis, have been reported.

4.9. Overdose

Symptoms of overdosage may include drowsiness disorientation and extrapyramidal reactions.

Anticholinergic, anti-parkinsonian drugs or antihistamines with anticholinergic properties may be helpful in controlling the extrapyramidal reactions. There is no specific antidote to domperidone, but in the event of overdosage, gastric lavage may be useful.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Domperidone is a dopamine antagonist and increases gastro-intestinal motility. It does not reach brain dopamine receptors, probably because it is unable to cross the blood brain barrier.

5.2. Pharmacokinetic properties

After oral administration, domperidone is rapidly and almost completely absorbed from the gastro-intestinal tract. Its systemic bioavailability is about 15% in fasting subjects and is increased when administered after food intake. Peak plasma concentrations of domperidone occur within half an hour with about 90% plasma protein binding

Domperidone is cleared from blood by extensive hepatic metabolism. About 30% of an oral dose is eliminated in urine in 24 hours, almost entirely as metabolites. The remainder of the dose is eliminated in faeces. It has a terminal elimination plasma half-life of 7.5 hours.

5.3. Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose monohydrate
Maize starch
Microcrystalline cellulose
Povidone K30
Sodium laurilsulfate
Magnesium stearate
Silica, colloidal anhydrous

6.2. Incompatibilities

None

6.3. Shelf life

36 months

6.4. Special precautions for storage

Do not store above 30°C.
Store in the original package.

6.5. Nature and contents of container

PVC/Aluminium blister packs
Pack sizes 28, 30, 56, 100 & 112.

6.6. Instructions for use and handling

None

7. MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Ltd
NLA Tower
Croydon

CRO OXT
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 12762/0087

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 December 2002

10. DATE OF REVISION OF THE TEXT