

Patient Information Leaflet for
DOMPERIDONE STOMACH DISCOMFORT RELIEF TABLETS
(Domperidone 10 mg)

Read all of this Leaflet carefully because it contains important information for you. This medicine is available without a prescription, for you to treat a mild condition without a doctor's help. Nevertheless, you still need to take this medicine carefully to get the best results from it.

- Keep this Leaflet. You may want to read it again
- Ask your pharmacist if you need more information or advice

Your medicine

Each film-coated tablet contains 10mg of the active ingredient domperidone. Each tablet also contains lactose monohydrate, microcrystalline cellulose, polyvidone, pregelatinised maize starch, maize starch, sodium lauryl sulphate and magnesium stearate. The film coating contains hydroxypropyl methylcellulose (E464), titanium dioxide (E171) and polyethylene glycol.

Stomach Discomfort Relief Tablets are available in blister packs of 4 and 10* tablets.
(*Only marketed pack sizes will feature in the printed leaflet)

Product Licence Holder: Generics [UK] Ltd, Station Close, Potters Bar, Herts, EN6 1TL.
Manufacturer: McDermott Laboratories Ltd t/a Gerard Laboratories, Baldoyle, Dublin 13, Republic of Ireland

What Domperidone is and what it is used for

Your medicine is in the form of a film-coated tablet. Domperidone belongs to a group of medicines called anti-emetics or anti-sickness medicine. Domperidone Stomach Relief Tablets are used to treat nausea (feeling sick), bloatedness, wind, or heartburn, following a meal.

Before you take your medicine

Do not take this medicine if:

- you have had an allergic or unusual reaction to domperidone or any of the tablet ingredients in the past
- you have a prolactinoma or pituitary tumour
- you have stomach or gut problems such as a blockage or bleeding
- you have liver or kidney problems.
- you have ever had heart problems including heart failure, a previous heart attack, angina (chest pains), or heart rhythm disorders including a rapid or slow or irregular heartbeat.

Your medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption, should not take this medicine.

Check with your doctor or pharmacist before taking your medicine if:

- you are pregnant or intend to become pregnant
- you are breast feeding
- you are already taking other medicines, including medicines prescribed by your doctor such as ketoconazole, to treat a fungal infection or erythromycin, an antibiotic.

Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30mg per day. Domperidone should be used at the lowest effective dose in adults and children.

How to take Domperidone Stomach Discomfort Relief Tablets

Adults (16 and over) and the elderly:

One 10mg tablet may be taken up to half an hour before a meal and at bedtime. No more than four tablets may be taken in a day.

Do not take the tablets for longer than 2 weeks. If symptoms persist, please consult your doctor.

Children (under 16 years of age):

Domperidone Stomach Discomfort Relief Tablets are not recommended for children under 16 years of age.

If you forget to take a dose take it as soon as you remember. If it is almost time for your next dose though, do not double the dose just carry on as before.

IF YOU TAKE TOO MUCH OF YOUR MEDICINE, contact your doctor or pharmacist or go to the nearest hospital casualty department immediately. Symptoms of overdose are mainly seen in babies and children and include agitation, fits, being drowsy or disorientated, muscle spasms in the face and eyes, muscle rigidity, and loss of consciousness.

Possible side effects

Rare side effects include stomach upset or cramps, swelling and tenderness of the breasts (even in men), leaking of milk from the breasts or stopping of periods (menstruation). Very rarely, patients may suffer from itchy red skin or an allergic reaction, which may be severe, causing swelling of the face, lips or tongue and difficulties in breathing. Other very rare side effects include diarrhoea, and abnormal liver function tests. A few patients have suffered from an unusual heartbeat, spasms in the muscles of the face and eyes, tremor, rigidity of the muscles and noticed a slowness in muscle movement. In addition, very rare cases of headaches, and nervousness have been reported, and very rare side effects mainly seen in children include drowsiness, fits (convulsions) and agitation.

Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30mg per day. Domperidone should be used at the lowest effective dose in adults and children.

If you should suffer from any of these unwanted side effects or any undesired effect please tell your pharmacist or doctor.

Storing your medicine

Keep your medicine out of the reach and sight of children
Store in a dry place below 25°C and protect from light.

Do not take this medicine after the expiry date shown on the carton. On the label you will find the letters 'Exp' followed by some numbers. These numbers are the date when the medicine is no longer fit for use. Do not use this medicine after this date.

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