

PATIENT INFORMATION LEAFLET - INFORMATION FOR THE USER

Domperidone 10mg Tablets

Domperidone

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

- What Domperidone is and what it is used for
- What you need to know before you take Domperidone
- How to take Domperidone
- Possible side effects
- How to store Domperidone
- Further information

1. What Domperidone is and what it is used for

Domperidone 10mg tablets (hereinafter referred to as Domperidone) are used in adults and children to treat nausea (feeling sick) and vomiting (being sick).

2. What you need to know before you take Domperidone

Do not take Domperidone if you:

- are allergic (hypersensitive) to Domperidone or any of the other ingredients of Domperidone Tablets (see section 6 for other ingredients)
- have a moderate or severe liver disease
- if your ECG (electrocardiogram) shows a heart problem called "prolonged QT corrected interval"
- if you have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure)
- if you have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood
- if you are taking certain medicines (see "Taking other medicines")
- have prolactinoma (a disease of the pituitary gland)
- have an underlying illness affecting the digestive system, for instance:-
 - a stomach or duodenal ulcer
 - a blocked or perforated gut
 - bowel motions (stools) that are often black, suggesting gut bleeding
 - frequent and severe stomach cramps.

Warnings and precautions

Before taking this medicine contact your doctor if you:

- suffer from liver problems - liver function impairment or failure (see "Do not take Domperidone if you")
- suffer from kidney problems (kidney function impairment or failure). It is advisable to ask your doctor for advice in case of prolonged treatment as you may need to take a lower dose or take this medicine less often, and your doctor may want to examine you regularly
- are under 12 years of age

- have or have had problems swallowing
 - have taken Domperidone for a long period.
- 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. The risk also increases when domperidone is given together with some drugs. Tell your doctor or pharmacist if you are taking drugs to treat infection (fungal infections or bacterial infection) and/or if you have heart problems or AIDS/HIV (see "Taking other medicines").

Domperidone should be used at the lowest effective dose in adults and children.

While taking domperidone, contact your doctor if you experience heart rhythm disorders such as palpitations, trouble breathing, loss of consciousness. Treatment with domperidone should be stopped.

Other medicines and Domperidone Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may stop Domperidone working properly or increase the risk of side effects.

Do not take Domperidone if you are taking medicine to treat:

- fungal infections such as azole anti-fungals, specifically oral ketoconazole, fluconazole or voriconazole
- bacterial infections, specifically erythromycin, clarithromycin, telithromycin, moxifloxacin, pentamidine (these are antibiotics)
- heart problems or high blood pressure (eg. amiodarone, dronedarone, quinidine, disopyramide, dofetilide, sotalol, diltiazem, verapamil)
- psychoses (eg. haloperidol, pimozide, sertindole)
- depression (eg. citalopram, escitalopram)
- gastro-intestinal disorders (eg. cisapride, dolasetron, prucalopride)
- allergy (eg. mequitazine, mizolastine)
- malaria (in particular halofantrine)
- AIDS/HIV (protease inhibitors)
- Cancer (eg. toremifene, vandetanib, vincamine)

Tell your doctor or pharmacist if you are taking drugs to treat infection, heart problems or AIDS/HIV.

It is important to ask your doctor or pharmacist if Domperidone is safe for you when you are taking any other medicines, including medicines obtained without a prescription.

You must tell your doctor or pharmacist if you are already taking any of the following:

- bromocriptine and pergolide (dopamine agonist) used to treat Parkinson's disease or hormonal imbalance
- medicines to treat overactive bladder, irritable bowel syndrome or diarrhoea
- strong painkillers like codeine or morphine
- rifampicin (antibiotic)
- medicines for the treatment of epilepsy
- sodium bicarbonate (an ingredient in some medicines for indigestion)
- cimetidine used to treat stomach ulcers.

Taking Domperidone with food and drink

Swallow the tablets with a drink of water 15 - 30 minutes before a meal.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicines.

(continued overleaf)

If you are pregnant, think you may be pregnant or are breast-feeding your baby, you should not take Domperidone. Small amounts of domperidone have been detected in breast milk. Domperidone may cause unwanted side effects affecting the heart in a breast-fed baby. Domperidone should be used during breast feeding only if your physician considers this clearly necessary. Ask your doctor for advice before taking this medicine.

Driving and operating machinery

There are no known effects of this medicine on your ability to drive or use machinery.

Important information about some of the ingredients in this product

These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

3. How to take Domperidone

Always take Domperidone exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Follow these instructions closely unless your doctor has advised you otherwise. Take your tablets 15 - 30 minutes before a meal or before you go to bed.

Duration of treatment

Symptoms usually resolve within 3-4 days of taking this medicine. Do not take Domperidone for longer than 7 days without consulting your doctor.

Adults and adolescents 12 years of age and older with a body weight of 35kg or more

The usual adult dose is one tablet taken up to three times per day, if possible before meals.

Do not take more than three tablets per day.

Children and adolescents from birth to a body weight of less than 35 kg

Tablets are not suitable for children weighing less than 35kg.

If domperidone is for a child, ask your doctor for the children's formulation.

If you take more Domperidone than you should:

If you have used or taken too much Domperidone, contact your doctor, pharmacist or the poison centre immediately, in particular if a child has taken too much. In the event of overdose, symptomatic treatment could be implemented. An ECG monitoring could be undertaken, because of the possibility of a heart problem called prolonged QT interval.

If you forget to take Domperidone

If you forget to take a tablet, take one as soon as you remember. If it is almost time for your next dose, wait until that is due and then continue as normal. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

If you notice any of the following serious side effects, stop taking Domperidone and contact your doctor immediately:

- allergic reactions such as skin rash, itching, shortness of breath, wheezing and/or swollen face
- irregular heartbeat
- abnormal muscle movements or posture, tremor (shaking), muscle stiffness or unusual eye movements.

If you notice any of the following side effects, stop taking Domperidone and speak to your doctor or pharmacist:

These side effects may occur uncommonly (less than 1 in 100 people)

- leaking of milky fluid from the breasts
- sore or painful breasts
- decreased sex drive
- weakness
- mild skin rash or hives

The frequency of these side effects is not known:

- breast growth in men
- absence of menstrual periods
- feeling anxious, agitated or nervous
- fits
- inability to pass urine
- increase in the level of a hormone called prolactin
- abnormal liver function tests

Disorders of the cardiovascular system: heart rhythm disorders (rapid or irregular heart beat) have been reported; if this happens, you should stop the treatment immediately.

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.

Other side effects which may occur commonly (less than 1 in 10 people) include:

- dry mouth

Other side effects which may occur uncommonly (less than 1 in 100 people) include:

- diarrhoea
- sleepiness
- headache

Domperidone may cause stomach cramps, but these usually only last for a short time.

If you have stomach cramps that last for more than a day speak to your doctor or pharmacist.

Unusual muscle movements, fits and agitation are seen more often in newborn babies, infants and young children than in adults.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Domperidone

Keep your tablets out of the sight and reach of children.

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

Do not use the tablets after the expiry date on the product packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Domperidone contains

Each tablet contains 10mg domperidone as domperidone maleate. It also contains lactose, maize starch, microcrystalline cellulose, povidone, sodium lauryl sulphate, magnesium stearate and colloidal anhydrous silica.

What Domperidone looks like and contents of the pack

Domperidone 10mg tablets are white, circular tablets with 'Dm10' stamped on one side. They are supplied in cartons of 30 and 100.

Marketing Authorisation Holder and Manufacturer

Manx Healthcare Ltd, Taylor Group House, Wedgnoek Lane, Warwick, CV34 5YA, United Kingdom

Distributed by Teva UK Ltd, Eastbourne, BN22 9AG

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