



Package leaflet: Information for the user

Domperidone 10mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Domperidone is and what it is used for
2. What you need to know before you take Domperidone
3. How to take Domperidone
4. Possible side effects
5. How to store Domperidone
6. Contents of the pack and other information

1. What Domperidone is and what it is used for

Domperidone 10mg tablets (hereinafter referred to as Domperidone) contains a medicine called domperidone which belongs to a group of medicines called 'dopamine antagonists'. This medicine is used to treat nausea (feeling sick) and vomiting (being sick) in adults and adolescents (12 years of age and older and weighing 35kg or more).

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

Talk to your doctor or pharmacist before taking this medicine 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.

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.

Adolescents weighing less than 35kg and children

Domperidone should not be given to adolescents 12 years of age and older weighing less than 35kg, or in any children less than 12 years of age, as it is not effective in these age groups.

Other medicines and Domperidone

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.

Domperidone Tablets and apomorphine

Before you use Domperidone Tablets and apomorphine, your doctor will ensure that you tolerate both medicines when used simultaneously. Ask your doctor or specialist for personalised advice. Please refer to the apomorphine leaflet.

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.

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. 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.

(continued overleaf)

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 using machinery

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

Domperidone contains lactose

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 or pharmacist has told you. 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.

If you take more Domperidone than you should:

If you have 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.

The signs of taking more than you should include feeling sleepy, confusion, uncontrolled movements (especially in children), which include unusual eye movement, unusual movements of the tongue or abnormal posture (such a twisted neck).

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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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, difficulty in swallowing or breathing, wheezing, and/or swelling of the hands, feet, ankles, face, lips or throat
- abnormal muscle movements or posture, tremor (shaking), muscle stiffness or unusual eye movements
- fit (seizure)
- 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.

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

Other side effects include:

Common (may affect up to 1 in 10 people)

- dry mouth

Uncommon (may affect up to 1 in 100 people)

- leaking of milky fluid from the breasts
- sore or painful breasts

- decreased sex drive
- weakness
- anxiety
- diarrhoea
- sleepiness
- headache

Not known (frequency cannot be estimated from the available data)

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

Some patients who have used Domperidone for conditions and dosages requiring longer term medical supervision have experienced the following unwanted effects: restlessness, swollen or enlarged breasts, unusual discharge from breasts, irregular menstrual periods in women, difficulty breastfeeding, depression, hypersensitivity.

Unusual muscle movements, feeling drowsy, nervous, agitated or irritable and fits 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. 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. Contents of the pack and other 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

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