

Domerid 10 mg Tablets

domperidone

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 Domerid is and what it is used for
2. What you need to know before you take Domerid
3. How to take Domerid
4. Possible side effects
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1 What Domerid is and what it is used for

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 35 kg or more.

2 What you need to know before you take Domerid

Do not take Domerid

- if you are **allergic to domperidone** or any of the other ingredients of this medicine (listed in section 6)
- if you have stomach bleeding or if you regularly have severe abdominal pain or persistent black stools (poo)
- if you have a blocked or perforated gut
- if you have a **prolactin-producing tumour of the pituitary gland** (prolactinoma)
- if you have a **moderate or severe liver disease**
- if your ECG (electrocardiogram) shows a **heart problem** called "prolonged QT interval"
- if you have or had a problem where your heart cannot pump the blood around 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 "Other medicines and Domerid").

Warnings and precautions

Domperidone should not be given to children under 12 years and to adolescents aged 12 years or more with a body weight of less than 35 kg, as the effectiveness in these age groups has not been established.

Before taking this medicine contact your doctor if you:

- suffer from liver problems (liver function impairment or failure) (see "Do not take Domerid").
- 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.

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 in those taking doses higher than 30 mg per day. The risk also increases when domperidone is given together with some medicines. Tell your doctor or pharmacist if you are taking medicines to treat infection (fungal infections or bacterial infection) and/or if you have heart problems or AIDS/HIV (see section other medicines and Domerid).

Domperidone should be used at the lowest effective dose (see "Possible side effects").

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 Domerid

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Domerid if you are taking medicines to treat:

- fungal infections such as pentamidine or azole anti-fungals, specifically itraconazole, oral ketoconazole, fluconazole, posaconazole or voriconazole
- bacterial infections, specifically erythromycin, clarithromycin, telithromycin, levofloxacin, moxifloxacin, spiramycin (these are antibiotics)
- heart problems or high blood pressure (e.g. amiodarone, dronedarone, ibutilide, disopyramide, dofetilide, sotalol, hydroquinidine, quinidine)
- psychoses (e.g. haloperidol, pimozide, sertindole)
- depression (e.g. citalopram, escitalopram)
- gastro-intestinal disorders (e.g. cisapride, dolasetron, prucalopride)
- allergy (e.g. mequitazine, mizolastine)
- malaria (in particular halofantrine, lumefantrine)
- AIDS/HIV such as ritonavir or saquinavir (these are protease inhibitors)
- cancer (e.g. toremifene, vandetanib, vincamine)
- Hepatitis C (e.g. telaprevir).

Do not take Domerid if you are taking certain other medicines (e.g. bepridil, diphemanil, methadone).

Tell your doctor or pharmacist if you are taking medicines to treat infection (such as azithromycin and roxithromycin), heart problems (such as verapamil and diltiazem), AIDS/HIV or Parkinson's disease.

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

Tell your doctor if you are taking antacids or other medicines that reduce stomach acid (such as cimetidine or sodium bicarbonate). These medicines can be taken if you are also taking domperidone but they should not be taken at the same time as they may affect how well domperidone works.

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

Domerid with food

Take Domerid before meals, as when taken after meals, the absorption of the medicine is slightly delayed (see "How to take Domerid").

Pregnancy and breast-feeding

It is not known whether the use of Domerid is harmful during pregnancy. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Only insufficient experience is available regarding use of Domerid in pregnant women. The potential risk for humans is not known. If you are pregnant, you should take Domerid only if your attending doctor deems it absolutely necessary.

Breast-feeding

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 using machines

Some patients have reported feeling dizzy or sleepy after taking Domerid. Do not drive or use machinery while taking Domerid until you know how Domerid affects you.

Domerid contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Domerid contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Domerid

Always take this medicine 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 Domerid before meals, as when taken after meals, the absorption of the medicine is slightly delayed.

Duration of treatment

The attending doctor decides on the duration of intake. Symptoms usually resolve within 3-4 days of taking this medicine. Do not take Domerid for longer than 7 days without consulting your doctor.

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

The usual dose is one tablet taken up to three times per day, if possible before meals. Take the tablet with some water or other liquid. Do not chew the tablet. Do not take more than three tablets per day.

If you take more Domerid than you should

If you have used or taken too much Domerid, contact your doctor, pharmacist or the poison center 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.

Information for the doctor: close observation of the patient, gastric lavage, administration of activated charcoal and general supportive measures are recommended.

Anticholinergics and anti-parkinsonian medicines may help to counteract the extrapyramidal disorders.

If you forget to take Domerid

Take your medicine 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 tablet.

4 Possible side effects

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

Uncommon (may affect up to 1 in 100 people):

- Involuntary movements of the face or

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arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm.

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

- Seizures
- A type of reaction that may occur soon after administration and is recognised by skin rash, itching, shortness of breath, and/or a swollen face
- A severe hypersensitivity reaction that may occur soon after administration that is characterised by hives, itching, flushing, fainting, and difficulty breathing among other possible symptoms.

Disorders of the cardiovascular system: heart rhythm disorders (rapid or irregular heartbeat) 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 30 mg per day. Domperidone should be used at the lowest effective dose.

Stop treatment with Domerid and contact your doctor immediately if you experience any of the unwanted events described above.

Other unwanted effects that have been observed with Domerid are listed below:

Common (may affect up to 1 in 10 people):

- Dry mouth.

Uncommon (may affect up to 1 in 100 people):

- Anxiety
- Agitation
- Nervousness
- Loss of interest in sex or diminished interest in sex
- Headache
- Sleepiness
- Diarrhoea
- Rash
- Itchiness
- Hives
- Painful or tender breasts
- Milk discharge from breasts
- A general feeling of weakness
- Feeling dizzy.

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

- Upward movement of the eyes
- Stopped menstrual periods in women
- Enlarged breasts in men
- Inability to urinate
- Changes in certain laboratory test results
- Restless legs syndrome (uncomfortable feeling, with an irresistible urge to move your legs, and sometimes arms and other parts of your body).

Some patients who have used Domerid for conditions and doses requiring medical oversight have experienced the following unwanted effects:

Restlessness; swollen or enlarged breasts, unusual discharge from breasts, irregular menstrual periods in women, difficulty breast-feeding, depression, hypersensitivity.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Domerid

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Domerid contains

The active substance is domperidone. Each tablet contains 10 mg domperidone (as domperidone maleate).

The other ingredients are microcrystalline cellulose, lactose monohydrate, magnesium stearate, starch, sodium lauryl sulfate, povidone K30 and colloidal anhydrous silica.

Advice to diabetics

Each tablet contains less than 0.01 carbohydrate exchange units.

What Domerid looks like and contents of the pack

The tablets are white, round, biconvex with inscription "Dm10" on one side.

Domerid is available in blister packs of 10, 20, 30, 50 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.
Rowa Pharmaceuticals Ltd., Newtown, Bantry, Co. Cork, Ireland.
Lek Pharmaceuticals d.d., Trimlini 2 D, 9220 Lendava, Slovenia.
LEK Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany: Domperidon HEXAL 10 mg tabletten

Ireland: Domerid 10 mg Tablets

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