

1.3.1.3 PACKAGE LEAFLET

Package leaflet: Information for the user

Domerid Relief 10 mg 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 because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

1. What Domerid Relief tablets are and what they are used for
2. What you need to know before you take Domerid Relief tablets
3. How to take Domerid Relief tablets
4. Possible side effects
5. How to store Domerid Relief tablets
6. Contents of the pack and other information

1 What Domerid Relief tablets are and what they are used for

This medicine contains domperidone, which is a gastric therapeutic and belong to the group of medicines called dopamine antagonists.

It 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 Domerid Relief tablets

Do not take Domerid Relief tablets

- if you are **allergic to domperidone** or any of the other ingredients of this medicine (listed in section 6).
- 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 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”)
- if you have gastrointestinal bleeding, mechanical obstruction or perforation.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Domerid Relief tablets.

Please contact your doctor before taking this medicine if you:

- suffer from liver problems (liver function impairment or failure) (see “Do not take this medicinal product”)
- 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 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) or Parkinson's disease (levodopa) and/or if you have heart problems or AIDS/HIV (see section other medicines and Domerid Relief tablets).

Domperidone should be used at the lowest effective dose in adults and children (see 4 “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 Relief tablets

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

Do not take Domerid Relief tablets if you are taking medicine to treat:

- fungal infections such asazole 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 (e.g. amiodarone, dronedarone, quinidine, disopyramide, dofetilide, sotalol, diltiazem, verapamil)
- 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)
- AIDS/HIV (protease inhibitors)
- cancer (e.g. toremifene, vandetanib, vincamine)

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

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

Domerid Relief tablets with food

If possible, take tablets before meals as when taken after meals, the absorption of the medicine is slightly delayed.

Pregnancy and breast-feeding

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 Relief tablets in pregnant women. The potential risk for humans is not known. If you are pregnant, you should take Domerid Relief tablets 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

Domerid Relief tablets have no or only a negligible influence on the ability to drive and use machines.

Domerid Relief tablets contain lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take this medicinal product.

3 How to take Domerid Relief tablets

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.

Adults and adolescents 12 years of age and older 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.

Renal dysfunction

In the presence of a severe renal dysfunction, the frequency of intake should be reduced to once or twice daily (see also "Take special care with Domerid Relief tablets").

Use in children and adolescents

The tablets are not indicated for use in children and adolescents from birth to bodyweight of less than 35 kg (see also "Take special care with Domerid Relief tablets").

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

Mode of administration

Take the tablets together with liquid (e.g. 1 glass of water) prior to meals.

If taken after meals, absorption of domperidone is somewhat delayed.

Duration of treatment

Symptoms usually resolve with 3-4 days of taking this medicine. Do not take Domerid Relief tablets for longer than 7 days without consulting your doctor.

If your symptoms persist please talk to your doctor.

If you take more Domerid Relief tablets than you should

If you have used or taken too much Domerid Relief tablets, contact your doctor, pharmacist or the poison centre immediately, in particular if a child has taken too much.

Symptoms of an overdose may be:

- agitation
- altered consciousness
- seizures
- somnolence
- disorientation
- motor disturbances

Information for your doctor:

There is no specific antidote for domperidone. 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.

Gastric lavage as well as the administration of activated charcoal may be of benefit in case of an overdose. Close medical monitoring and supportive measures are recommended. Anticholinergics and anti-parkinsonian medications can be used as antidote in motor disturbances (extrapyramidal reactions).

If you forget to take Domerid Relief tablets

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.

If you stop taking Domerid Relief tablets

Do not stop treatment without talking to your doctor first.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Domerid Relief tablets can cause side effects, although not everybody gets them.

If you experience any of the following, stop using the medicine and seek immediate medical help:

- Fits or seizures.
- Involuntary movements of the face or arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm.
- Allergic reactions: signs of allergy include rash (such as hives), itching, shortness of breath, wheezing and or swollen face or neck, flushing or fainting.
- Heart rhythm disorder

Possible side effects are:**Rare**, may affect up to 1 in 1,000 people:

- Elevated prolactin levels (a hormone that stimulates the milk production in the breast, see below)
- Gastrointestinal complaints, including in very rare cases transient intestinal cramps
- Milky secretion from the mammary gland (in women)
- Missed monthly period
- Enlargement of the breast (in men)

Very rare, may affect up to 1 in 10,000 people:

- Allergic reactions (e.g. allergic shock, shortness of breath, wheezing and/or tissue swelling predominantly affecting the face); if this happens, you should stop the treatment immediately.
- Agitation, nervousness
- Motor disturbances (extrapyramidal side effects), seizures, somnolence, headache
- Heart rhythm disorder. If this happens, you should stop the treatment immediately.
- Diarrhoea
- Nettle rash, itching (pruritus), reddening (rash)
- Abnormal liver test values

As the hypophysis (pituitary gland) is located outside the blood-brain barrier, domperidone may cause an increase in the prolactin level. In rare cases, this increase in the hormone stimulating milk production can lead to side effects affecting the hormone regulation through the brain, such as milk flow (galactorrhoea), breast growth in men (gynaecomastia) and missed monthly period (amenorrhoea).

Side effects with disordered course of motions (so-called extrapyramidal side effects) are very rare in newborns and toddlers and occur in adults only in exceptional cases. These side effects spontaneously and completely disappear as soon as treatment is terminated. Other central nervous system-related effects of seizures, agitation, and somnolence also are very rare and primarily reported in infants and children.

Not known, frequency cannot be estimated from the available data

- 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 30 mg per day. Domperidone should be used at the lowest effective dose in adults and children.
- Restless leg syndrome (may exacerbate if you are a patient with Parkinson's disease)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 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 Relief tablets

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 packaging. The expiry date refers to the last day of that month.

Storage conditions

Do not store above 30°C.

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

6 Contents of the pack and other information

What Domerid Relief tablets contain

The active substance is: **domperidone**

One tablet contains 12.72 mg domperidone maleate, corresponding to 10 mg domperidone.

The other ingredients are: microcrystalline cellulose, lactose monohydrate, magnesium stearate (Ph.Eur.), maize starch, sodium laurilsulfate, povidone K 30, colloidal anhydrous silica

Advice to diabetics

1 tablet contains less than 0.01 carbohydrate exchange units.

What Domerid Relief tablets look like and contents of the pack

The tablets are white, round, biconvex with inscription "Dm 10" on one side.

Domerid Relief tablets are available in blister packs of 10 and 20 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.

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

Ireland: Domerid Relief 10 mg Tablets

This leaflet was last revised in 02/2015.