

PACKAGE LEAFLET: INFORMATION FOR THE USER

Domperidone 10mg Tablets

(domperidone maleate)

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.

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

1. WHAT DOMPERIDONE TABLETS ARE AND WHAT THEY ARE USED FOR

Domperidone Tablets contain domperidone as the active ingredient, which belongs to a group of medicines called 'dopamine antagonists'.

Domperidone works by helping to move food faster through your food pipe (oesophagus), stomach and gut. This is so that it does not stay in the same place for too long. It also helps stop food flowing the wrong way back up your food pipe.

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).

You must talk to a doctor if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOMPERIDONE TABLETS

Do not take Domperidone Tablets if you:

- are allergic (hypersensitive) to domperidone or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- have a tumour of the pituitary gland called a prolactinoma.
- have or think you may have a serious intestinal problem such as internal bleeding (symptom being persistent black, tarry bowel motions), or an obstruction or perforation of the stomach or intestine (usually this involves severe stomach cramps)
- have a moderate or severe liver disease
- your ECG (electrocardiogram) shows a heart problem called "prolonged QT corrected interval"
- have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure).
- have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood.
- are taking certain medicines (see "Other medicines and Domperidone tablets")
- have or may have a rare tumour of the adrenal gland (pheochromocytoma) because it could elevate your blood pressure.

Do not take domperidone tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking domperidone if you suffer from:

- liver problems (liver function impairment or failure) (see "Do not take Domperidone Tablets if")
- 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.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Domperidone. Do this even if they have applied in the past. 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) and/or if you have heart problems or AIDS/HIV (see "other medicines and Domperidone Tablets").

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.

Adolescents weighing less than 35 kg and children

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

Other medicines and Domperidone tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you can buy without a prescription, including herbal medicines. This is because Domperidone tablets can affect the way some other medicines work. Also, some medicines can affect the way Domperidone tablets work.

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 (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)
- Angina pectoris (e.g. bepridil)
- Hyperhidrosis-excessive sweating (e.g. diphemanil)
- Opioid dependence (e.g. methadone)

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

Domperidone and apomorphine

Before you use Domperidone 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.

It is important to ask your doctor or pharmacist if domperidone is safe for you when you are taking or have recently taken any other medicines, even those not prescribed by a doctor, including any of the following:

- opioid analgesics, used to treat pain,
- antimuscarinics, used to treat bladder or gastrointestinal disorders
- amantadine, used to treat viral infections
- bromocriptine or cabergoline, used for the treatment of pituitary tumours or Parkinson's disease

Taking Domperidone Tablets with food and drink

The tablets should be taken before meals, as when taken after meals the absorption of the medicine is slightly delayed.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking Domperidone if:

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding. It is best not to take Domperidone if you are 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.

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

Domperidone can affect your ability to drive or use machinery as it makes you sleepy. Do not drive while taking this medicine until you know how it affects you.

Domperidone Tablets contains lactose

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

3. HOW TO TAKE DOMPERIDONE TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Duration of treatment

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

Taking this medicine

For oral use only.

The tablets must be swallowed with a glass of water.

Take the tablets 15 to 30 minutes before meals and, if needed, before you go to bed. Do not crush or chew them.

Follow these instructions closely unless your doctor has advised you otherwise.

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

The recommended dose is:

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.

Do not take more than three tablets per day.

Domperidone tablets are not suitable for children under 12 years of age and older with a body weight of less than 35kg.

People with kidney problems

Your doctor may tell you to take a lower dose or to take the medicine less often.

Your doctor may advise you to take your medicine in a different way, so you should always follow your doctor's advice about how and when to take your medicine and always read the label. If you feel that the effect of Domperidone 10mg Tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more Domperidone Tablets than you should

- If you have used or taken too much Domperidone, contact your doctor, pharmacist or the poison centre at your nearest hospital casualty department immediately, or go to the nearest hospital, in particular if a child has taken too much. Take the carton and any tablets left with you. This is so the doctors know what you have taken. In the event of overdose, symptomatic treatment could be implemented. You may be given active charcoal, which can prevent the absorption of domperidone, if taken soon after having taken the overdose. 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, confused, uncontrolled movements which include unusual eye movements, unusual movements of the tongue or abnormal posture (such as a twisted neck).

If you forget to take Domperidone Tablets

- If you forget to take Domperidone 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 dose.

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

4. POSSIBLE SIDE EFFECTS

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

Stop taking Domperidone tablets and see your doctor or go to a hospital straightaway if you:

- Get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to Domperidone tablets.
- Notice any uncontrolled movements. These include irregular eye movements, unusual movements of the tongue, and abnormal posture such as a twisted neck, trembling and muscle stiffness. This is more likely to happen in children. These symptoms should stop once you stop taking Domperidone tablets.
- Have a very fast or unusual heartbeat. This could be a sign of a life-threatening heart problem.
- Have a fit (seizure)

Other side effects include:

Common (affects less than 1 in 10 people)

- Dry mouth

Uncommon (affects less than 1 in 100 people)

- Lowering of sexual drive (libido) in men
- Feeling anxious
- Diarrhoea

- Feeling agitated or irritable
- Feeling more nervous than usual
- Feeling drowsy
- Headaches
- A general feeling of weakness
- Itchy skin. You may also have a rash
- Painful or tender breasts
- Unusual production of breast milk in men and women

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 tablets 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 tablets should be used at the lowest effective dose in adults and children.
- Abnormal eye movements
- Feeling the urge to move your legs, arms or other parts of your body (restless legs syndrome). These symptoms may become worse in patients suffering from Parkinson's disease.
- Inability, or difficulty to urinate
- Breast enlargement or swelling in men
- In women, menstrual periods may be irregular or stop
- A blood test shows changes in the way your liver is working. If you have a blood test to check your liver function tell your doctor or nurse that you are taking Domperidone.

Some patients who have used Domperidone tablets 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.

Side effects such as feeling drowsy, nervous, agitated or irritable or having a fit are more likely to happen in children.

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 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 TABLETS

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

Do not store above 25°C. Store in the original package.

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

Do not use this medicine if you notice signs of deterioration.

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 Domperidone Tablets contains

The active substance is domperidone maleate, equivalent to 10 mg domperidone.

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

What Domperidone Tablets looks like and contents of the pack

The tablets are white, round, biconvex and uncoated with "Dm 10" marked on one side.

They are available in blister packs of 30 and 100 tablets. Not all pack sizes may be marketed.

This leaflet was last revised in September 2025.

PL 44041/0011

Marketing Authorisation Holder and Manufacturer:

NOUMED LIFE SCIENCES LIMITED
 Noumed House, Shoppenhangers Road
 Maidenhead, Berkshire, SL6 2RB, United Kingdom.

POM

To listen to or request a copy of this leaflet in Braille, large print or audio please call, 020 33998960 (UK only)

Please be ready to give the following information:

Product name
 Domperidone 10 mg Tablets

Reference number
 PL 44041/0011

Colours

■ Black

Signature of Author:				Font Type & Size	Heading Futura MD BT - 12 pts	
Signature of RA:					Body Futura MD BT - 8 pts	
				Title: Art Work Approval Form		
Product	Domperidone			Specification:	n/a	
Customer	NOUMED LIFE SCIENCES LIMITED, UK					
Reason for Issue	psusa update			Colours:	black	
				Dimensions:	280 x 275 mm	
PL No.	PL 44041/0011	Pharmacode No.	n/a	No. of Folds (only for PIL)	n/a	n/a
Item Code	LDOM00/05	Layout No.:	n/a			