

**PACKAGE LEAFLET: INFORMATION FOR USER****DOMPERIDONE 10mg 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 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 active ingredient called Domperidone and belongs to a class of medicine called anti-emetics.

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 Domperidone Tablets****Do not take Domperidone Tablets if:**

- you are allergic (hypersensitive) to domperidone or any of the other ingredients of this medicine (listed under section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you have a moderate or severe liver disease
- your ECG (electrocardiogram) shows a heart problem called “prolonged QT corrected interval”

- 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).
- you have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood.
- you are taking certain medicines (see “Other medicines and Domperidone Tablets”)
- have a disorder known as phenylketonuria (a metabolic disorder) orodispersible tablets should not be used as they contain aspartamine
- you have a tumour of the pituitary gland (prolactinoma)
- have stomach bleeding or if you regularly have severe abdominal pain or persistent black stools (poo)
- have a blocked or perforated gut
- you have or may have a rare tumour of the adrenal gland (pheochromocytoma) because it could elevate your blood pressure.

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

**Warnings and Precautions:**

Talk to your doctor or pharmacist or nurse before taking Domperidone Tablets if you:

- suffer from liver problems (liver function impairment or failure) (see “Do not take Domperidone Tablets if”)
- 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 domperidone 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 tablets.

Do this even if they have applied in the past.

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 section other medicines and Domperidone Tablets).

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 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 or might take any other medicines. This includes medicines you can buy without a prescription, including herbal medicines. This is because Domperidone can affect the way some other medicines work. Also, some medicines can affect the way Domperidone works

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

- fungal infections, e.g., pentamidine or azole anti-fungals, specifically itraconazole, oral ketoconazole or fluconazole, posaconazole or voriconazole
- bacterial infections, specifically erythromycin, clarithromycin, telithromycin, moxifloxacin, levofloxacin, pentamidine, spiramycin (these are antibiotics)
- heart problems or high blood pressure (e.g., amiodarone, dronedarone, quinidine, disopyramide, dofetilide, sotalol, hydroquinidine, diltiazem, verapamil, ibutilide)
- 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)
- parkinson’s disease (e.g. levodopa)
- cancer (e.g., toremifene, vandetanib, vincamine)
- Hepatitis C (e.g., telaprevir)

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

**Domperidone and apomorphine**

Your doctor will decide how long you will need to take this medicine.

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 any other medicines, including medicines obtained without prescription.

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

**Domperidone Tablets with food, drink and alcohol**

It is recommended to take domperidone tablets before meals, as when taken after meals the absorption of the medicine is slightly delayed

**Pregnancy, breast-feeding and fertility****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. It is not known whether the use of this medicine is harmful during pregnancy.

**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**

At normal doses, this medicine does not affect your ability to drive or use machines.

If you notice symptoms of drowsiness, disorientation and lack of co-ordination do not drive or use machines.

**Domperidone Tablets contain lactose**

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

**Information on sodium content**

Domperidone Tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’.

### 3. How to take Domperidone 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. Take this medicine before meals, as when taken after meals, the absorption of the medicine is slightly delayed.

#### Duration of treatment:

Your doctor will decide how long you will need to take this medicine. 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

- Swallow the tablets whole with a drink of water
- Take the tablets 15 to 30 minutes before a meal
- Do not crush or chew them

#### The usual dose is:

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

Tablets 10 mg -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.

#### People with kidney problems

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

#### 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, 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. An ECG monitoring could be undertaken, because of the possibility of a heart problem called prolonged QT interval.

**Symptoms of overdose are:** sleepiness, confusion, uncontrolled movements (especially in children) 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

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.

### 4. Possible side effects

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

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

- Involuntary movements of the face or 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 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.

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

#### Other side effects include:

#### Common (affects less than 1 in 10 people)

- Dry mouth

#### Uncommon (affects less than 1 in 100 people)

- Loss of interest in sex or diminished interest in sex
- Anxiety
- Agitation
- Nervousness
- Headache
- Sleepiness

- Diarrhoea
- Rash
- Itchiness
- Hives
- Painful or tender breasts
- Unusual production of breast milk in men and women
- A general feeling of weakness
- Feeling dizzy

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

- Feeling agitated or irritable
- Feeling more nervous than usual
- Abnormal eye movements
- Inability to urinate
- 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.
- Breast enlargement in men
- In women, menstrual periods may be irregular or stop
- A blood test shows changes in the way your liver is working.

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 breast-feeding, 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, 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 Website: [www.mhra.gov.uk/yellowcard](http://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 out of the sight and reach of children.

- This medicinal product does not require any special temperature storage condition.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- 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 to protect the environment.

### 6. Contents of the pack and other information

#### What Domperidone Tablet contains

- Each tablet contains 10mg of the active substance Domperidone (as Domperidone maleate).
- The other ingredients are: lactose monohydrate, maize starch, povidone, sodium laurylsulfate, microcrystalline cellulose, colloidal anhydrous silica and magnesium stearate.

#### What Domperidone tablets looks like and contents of the pack

- Domperidone Tablets are white round biconvex tablets with 'BL' debossed on one side and '10' debossed on the other.
- The tablets are available in pack sizes of 10, 20, 30, 50 or 100 tablets. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

Bristol Laboratories Ltd,  
Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire,  
United Kingdom, HP4 1EG  
Telephone: 0044 (0)1442 200922  
Email: [info@bristol-labs.co.uk](mailto:info@bristol-labs.co.uk)

#### Manufacturer

Bristol Laboratories Limited  
Unit 5, Traynor Way, Whitehouse Business Park,  
Peterlee, SR8 2RU, United Kingdom

#### Domperidone 10mg Tablets, PL 17907/0096

#### This leaflet was last revised in September 2025

To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address ( telephone or email) above.

V20 25-09-25 D0

XXXXX