

PATIENT INFORMATION LEAFLET
DOMPERIDONE 1mg/ml ORAL SUSPENSION

▼ 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.

This product is available as the above name but will be referred to as Domperidone throughout the following leaflet:

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

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

The active ingredient in this medicine is called domperidone. This 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 in adults and in children to treat nausea (feeling sick) and vomiting (being sick).

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 (listed in section 6: Contents of the pack and other information). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have a tumour of the pituitary gland (prolactinoma).
- You have a blockage or tear in your intestines.
- You have black, tarry bowel motions (stools) or notice blood in your bowel motions. This could be a sign of bleeding in the stomach or intestines.
- 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")

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

Before taking this medicine contact your doctor 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.

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.

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").

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.

Other medicines and Domperidone:

Please 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 can affect the way some other medicines work. Also, some medicines can affect the way Domperidone works.

Do not take Domperidone Oral Suspension 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)

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

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. Medicines that reduce stomach acid should be taken after a meal.

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.

Taking Domperidone with food and drink

It is recommended to take Domperidone 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.

Driving and using machines:

Domperidone does not affect your ability to drive or use machines.

Important information about some of the ingredients of Domperidone:

This medicine contains sorbitol. If you have been told that you cannot digest or tolerate some sugars, talk to your doctor before taking Domperidone.

This medicine also contains methylhydroxybenzoate (E218) and propylhydroxybenzoate (E216). These substances may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

3. HOW TO TAKE DOMPERIDONE

Follow these instructions closely unless your doctor has advised you otherwise. You should check with your doctor or pharmacist if you are not sure.

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

- Take this medicine by mouth.
- **Adults and adolescents:** take your medicine using the plastic measuring cup provided with Domperidone. This cup is marked in ml (millilitres) to help you measure out the correct amount of this medicine.
- **Children weighing under 35kg:** should be given Domperidone using a suitably graduated oral syringe. Your doctor or pharmacist will supply you with this syringe. If you are not supplied with an oral syringe please speak to your doctor or pharmacist.
- Take your medicine 15 to 30 minutes before a meal.

The usual dose is:

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

The usual dose is 10 ml taken up to three times per day, if possible before meals. Do not take more than 30 ml per day.

- **Children and adolescents from birth to a body weight of less than 35kg**

Your doctor will work out the dose. This will depend on the weight of your child. Give the dose maximum 3 times a day, if possible before meals/feeding. Do not give more than 3 times in a 24 hour time period.

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 than you should:

- If you have used or taken too much Domperidone, contact your doctor, pharmacist or the poisons unit at your nearest hospital casualty department immediately in particular if a child has taken too much. Take the carton and bottle containing any remaining medicine 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.
- The signs of taking more than you should include feeling sleepy, confused, 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:

- If you forget to take Domperidone, take it as soon as you remember.
- However if it is almost time for the 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, Domperidone can have side effects, although not everybody gets them.

Stop taking Domperidone 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.
- You 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.
- You have a very fast or unusual heartbeat. This could be a sign of a life-threatening heart problem.
- You 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
- Feeling drowsy
- Headaches
- Diarrhoea
- Itchy skin. You may also have a rash
- Unusual production of breast milk in men and women
- Painful or tender breasts
- A general feeling of weakness

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.
- Feeling agitated or irritable
- Feeling more nervous than usual
- Abnormal eye movements
- Inability to urinate
- 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 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, 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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOMPERIDONE

- Keep out of the sight and reach of children.
- Do not store above 30°C.
- Do not take Domperidone Oral Suspension after the expiry date stated on the pack.
- Ask your pharmacist how to dispose of medicines you no longer need. Do not dispose of medicines by flushing down a toilet or sink, or by throwing them out with your normal household rubbish. This will help to protect the environment.
- If the liquid solution becomes decoloured or shows signs of deterioration, you should seek advice of your pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Domperidone contains

Each ml contains 1mg Domperidone as the active ingredient. It also contains sorbitol, microcrystalline cellulose E460 and carmellose sodium, methylhydroxybenzoate E218, propylhydroxybenzoate E216, sodium saccharin E954, polysorbate 20, sodium hydroxide and purified water.

What Domperidone looks like and contents of the pack

Each pack contains a white coloured suspension in a 200ml white polyethylene bottle with a child resistant, tamper-evident polyethylene screw cap, a graduated polypropylene measuring cup and a cream coloured 1.25ml spoon.

OR

Each pack contains a white coloured suspension in a 200ml white polyethylene bottle with a child resistant, tamper-evident polyethylene screw cap, a graduated polypropylene measuring cup.

PL No: 15814/1008 Domperidone 1mg/ml Oral Suspension

POM

Domperidone is manufactured by Laboratorios Dr. Esteve S.A., Avda Mare de Deu de Montserrat, 221 - 08041 Barcelona, Spain **OR** Laboratorios Dr. Esteve S.A., C/Sant Marti, s/n. Pol. Industrial La Roca, 08107 Martorelles (Barcelona), Spain. Procured from within the EU and repackaged by the Product Licence holder: OPD Laboratories Ltd, Unit-6 Colonial Way, Watford, Herts WD24 4PR.

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