PATIENT INFORMATION LEAFLET

DOMPERIDONE 1 mg/ml ORAL SUSPENSION

LAETUS CODE

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 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 name of your medicine is Domperidone 1mg/ml Oral Suspension (called domperidone in this leaflet). The active ingredient in this medicine is called domperidone. This belongs to a group of medicines called 'dopamine antagonists'.

This medicine is used to treat nausea (feeling sick) and vomiting (being sick) in adults and adolescents (12 years of age and older weighing 35 kg or more).

2. What you need to know before you take Domperidone

Do not take domperidone if:
- You are allergic 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.
- You have a tumour of the pituitary gland (prolactinoma).
- You have or may have a rare tumour of the adrenal gland (pheochromocytoma) because it could elevate your blood pressure.
- 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.

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

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, AIDS/HIV or Parkinson's disease.

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.

<u>Domperidone and apomorphine</u>

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

Domperidone Oral Suspension contains sorbitol, methylhydroxybenzoate and propylhydroxybenzoate
- Each 5 ml contains 2.275 g of sorbitol. If you have been told that you cannot digest or tolerate some sugars, talk to your doctor before taking domperidone.

- Each 5 ml contains 9 mg of methylhydroxybenzoate (E218) and 1 mg of propylhydroxybenzoate (E216). These substances may cause allergic reactions (possibly delayed).

3. How to take Domperidone

Follow these instructions closely unless your doctor has advised you otherwise. 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 within 3-4 days of taking this medicine. Do not take Domperidone Oral Suspension for longer than 7 days without consulting your doctor.

Taking this medicine
- Take this medicine by mouth.
- **Adults and adolescents 12 years of age and older and with a body weight of 35 kg or more:** take your medicine using the plastic measuring cup provided with Domperidone Oral Suspension. This cup is marked in ml (millilitres) to help you measure out the correct amount of this medicine.
- This product is not suitable for children under 12 years of age and older with a body weight of less than 35 kg.
- 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.

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 Oral Suspension, contact your doctor, pharmacist or the poisons unit at your nearest hospital casualty department immediately. 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 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, this medicine 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. 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 agitated or irritable
- Feeling more nervous than usual
- 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 adolescents 12 years of age and older.
- 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 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.

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 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

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the pack.
- Do no 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 1mg/ml Oral Suspension contains
Domperidone 1mg/ml Oral Suspension contains domperidone (the active ingredient). It also contains sorbitol, microcrystalline cellulose and carmellose sodium, methylhydroxybenzoate, propylhydroxybenzoate, sodium saccharin, polysorbate 20, sodium hydroxide and water.

What Domperidone 1mg/ml Oral Suspension looks like and contents of the pack
Each pack contains a 200 millilitre bottle of a white coloured liquid suspension.

Marketing Authorisation Holder
Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom.

Manufacturer
Sofarimex - Industria Quimica e Farmacêutica S.A.
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