Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

1. WHAT DOMPERIDONE IS AND WHAT IT IS USED FOR

The name of your medicine is Domperidone Oral Suspension (domperidone 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 and vomiting (being 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, swelling 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 should be a sign of bleeding in 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 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 high 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.

3. 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. 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.

4. INTERACTIONS WITH OTHER MEDICINES

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.

5. POSSIBLE ADVERSE EFFECTS

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.

6. ADVICE ON USE WITH OTHER MEDICINES

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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
• Take 10 ml given up to three times per day, provided you have eaten within the previous hour. 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 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 rashes and blisters. This may mean you have 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 if 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 desire (libido) in men
• Feeling anxious
• Feeling agitated or irritable
• Feeling more nervous after eating
• Feeling drowsy
• Headache
• Dizziness
• 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.
• Irritability or unusual behaviour
• 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; swelling or enlargement of the heart
• Unusual discharge from breasts, irregular menstrual periods in women, difficulty breastfeeding, depression, hypersensitivity.

Reporting of side effects
If you or any of your 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 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 not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use.

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, methyl-p-hydroxybenzoate, propyl-hydroxybenzoate, 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 coloured liquid suspension.

Marketing Authorisation Holder

Manufacturer
Sofarimex - Indústria Química e Farmacêutica Ltda.
Av. das Indústrias - Atos do Colaride
Agualva
2735-213 Cacém
Portugal

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