

## Package leaflet: Information for the patient

### Peptomet 10 mg Film-coated Tablets Domperidone

▼ 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Peptomet is and what it is used for
2. What you need to know before you take Peptomet
3. How to take Peptomet
4. Possible side effects
5. How to store Peptomet
6. Contents of the pack and other information

#### **1. What Peptomet is and what it is used for**

Peptomet is a medicine which contains domperidone. It belongs to a group of medicines called 'dopamine antagonists'.

This medicine is used in adults and in adolescents to treat nausea (feeling sick) and vomiting (being sick).

#### **2. What you need to know before you take Peptomet**

This medicine is suitable for most adults and adolescents 12 years of age and older with a body weight of 35 kg or more, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

#### **Do not take Peptomet**

- if you are allergic (hypersensitive) to domperidone or any of the other ingredients of Peptomet 10 mg Film-Coated Tablets (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.
- if you have a tumour of the pituitary gland (prolactinoma).
- if you have a blockage or tear in your intestines.

- if 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.
- if you have a moderate or severe liver disease .
- if your ECG (electrocardiogram) shows a heart problem called “prolonged QT corrected interval”.
- if 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).
- if you have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood.
- if you are taking certain medicines (see “Other medicines and Peptomet”).

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

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Peptomet:

- if you suffer from liver problems (liver function impairment or failure) (see “Do not take Peptomet”).
- 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 Peptomet. 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 Peptomet”).

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

While taking domperidone, contact your doctor if you experience heart rhythm disorders such as palpitations, trouble breathing, and loss of consciousness. Treatment with domperidone should be stopped.

### **Other medicines and Peptomet**

Do not take Peptomet if you are taking medicine to treat:

- fungal infections such asazole 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).

### **Peptomet and apomorphine**

Before you use Peptomet 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.

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

Tell your doctor or pharmacist if you are taking, have recently taken or plan to take any other medicines, including medicines obtained without prescription.

### **Peptomet with food, drink and alcohol**

It is recommended to take Peptomet 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 Peptomet if you are pregnant, might become pregnant or think you may be pregnant.

Talk to your doctor or pharmacist before taking Peptomet if you are breast-feeding. It is best not to take Peptomet 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:**

You may have less control over your movements whilst taking Peptomet. If this happens do not drive or use ant tools or machines.

### **Peptomet contains lactose.**

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

## **3. How to take Peptomet**

Always take this medicine exactly as your doctor or pharmacist has told you. 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 Peptomet 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.

**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.

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

Tablets are not suitable for children and adolescents weighing less than 35 kg.

**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 Peptomet than you should**

If you have used or taken too much Peptomet, contact your doctor, pharmacist or the poison centre 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.

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 Peptomet**

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, Peptomet can have side effects, although not everybody gets them.

**If you experience any of the following, stop using the medicine and seek immediate medical help:**

- fits (seizure).
- fast or unusual heart-beat. This could be a sign of a life-threatening heart problem.
- 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 Peptomet.
- 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 Peptomet.

## **Other**

Common (affects less than 1 in 10 people)

- dry mouth.

Uncommon (affects less than 1 in 100 people)

- feeling anxious.
- lowering of sexual drive (libido) in men.
- feeling drowsy.
- headaches.
- diarrhoea.
- itchy skin. You may also have a rash.
- painful or tender breasts.
- unusual production of breast milk in men and women.
- a general feeling of weakness.

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

- feeling agitated or irritable.
- feeling more nervous than usual.
- abnormal eye movement.
- 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.
- 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.

Some patients who have used Peptomet 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

## **Cyprus**

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## **5. How to store Peptomet**

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

Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Store below 25°C. Protect from light and moisture.

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

### **What Peptomet contains**

- The active ingredient is domperidone. Each tablet contains 10mg domperidone.
- The other ingredients are: Microcrystalline cellulose, lactose monohydrate, maize starch, povidone, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, talc, hypromellose, polyethylene glycol 400, titanium dioxide E171.

### **What Peptomet look like and contents of the pack**

Peptomet 10 mg film-coated tablets: White, round, film-coated tablets

#### **Pack Size**

Peptomet 10 mg film-coated tablets:

PVC/Aluminium blisters. Pack-size of 30, 100 and 1000.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder & Manufacturer:**

Remedica Ltd,

Aharnon Str., Limassol Industrial Estate,

3056, Limassol, Cyprus.

**This leaflet was last revised in 09/2017**

*For internal use: cy-pl-peptomet-fc-tabs-a1*