

Package leaflet: Information for the patient

Peptomet 10 mg film-coated 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, 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 (listed in section 6). 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 30 mg 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 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).

Peptommet and apomorphine

Before you use Peptommet 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.

Peptommet with food, drink and alcohol

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

Talk to your doctor or pharmacist before taking Peptommet if you are breast-feeding. It is best not to take Peptommet 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 Peptommet. If this happens do not drive or use any tools or machines.

Excipients warnings

Peptommet contains sodium.

This medicine contains less than 1 mmon sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Peptommet 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 Peptommet

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 Peptommet 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 Peptommet than you should

If you have used or taken too much Peptommet, contact your doctor, pharmacist or the poison center 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 Peptommet

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Peptommet 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.
- feeling agitated or irritable.
- feeling more nervous than usual.
- 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)

- abnormal eye movement.
- inability to urinate.
- restless legs syndrome (uncomfortable feeling, with an irresistible urge to move parts of your legs, and sometimes arms and other parts of your body).
- 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 via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

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.

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

Shelf life:

5 years.

6. Contents of the pack and other information

What Peptomet contains

- The active substance is domperidone.

Each film-coated tablet contains 10 mg domperidone.

- The other ingredients are: cellulose microcrystalline, lactose monohydrate, maize starch, povidone, sodium starch glycolate (type A), silica colloidal anhydrous, magnesium stearate, talc, hypromellose, macrogol 400, titanium dioxide.

See section 2 ‘Excipients warnings’.

What Peptomet look like and contents of the pack

White, round, film-coated tablets.

Pack sizes:

Cardboard box containing Aluminium-PVC blisters of 10 film-coated tablets.

Pack size of 30 film-coated tablets (3 blisters x 10 tablets).

Marketing Authorisation Holder and Manufacturer:

Remedica Ltd,

Aharon Str., Limassol Industrial Estate,

3056, Limassol, Cyprus.

This leaflet was last revised in October 2023.

For internal use only: am-pl-peptomet-fc-tabs-a2