

Package leaflet: Information for the user
Domperidone 1mg/ml Oral Suspension

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

1. What Domperidone Suspension is and what it is used for

The name of your medicine is Domperidone 1mg/ml Oral Suspension (called Domperidone Suspension 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 and weighing 35kg or more).

2. What you need to know before you take Domperidone Suspension

Do not take Domperidone suspension if you:

- are allergic (hypersensitive) to domperidone or any of the other ingredients of Domperidone Suspension (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
- have a tumour of the pituitary gland (prolactinoma)
- have a blockage or tear in your intestines
- 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 “Taking other medicines”)

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

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 this Domperidone suspension 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
- are taking a medicine called levodopa, see ‘Other medicines and Domperidone Suspension’.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Domperidone Suspension. Do this even if they have applied in the past.

Domperidone Suspension 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 Domperidone Suspension).

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 35kg 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 Suspension

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

Do not take Domperidone Suspension if you are taking medicines 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, the antidepressant nefazadone, levodopa, a medicine used to treat Parkinson's symptoms, or aprepitant, a medicine used to reduce nausea associated with cancer chemotherapy.

Antacids or antisecretory agents should not be taken simultaneously with Domperidone Suspension. Domperidone Suspension should be taken before meals and antacids or antisecretory agents after meals.

Domperidone Suspension and apomorphine:

Before you use Domperidone Suspension 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 Suspension is safe for you when you are taking any other medicines, including medicines obtained without prescription.

Domperidone Suspension 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 breastfeeding

Talk to your doctor or pharmacist before taking Domperidone Suspension if you:

- are pregnant, might become pregnant or think you may be pregnant
- 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.

This medicine contains less than 1 mmol sodium (23 mg) per 10ml dose, that is to say essentially 'sodium-free'.

Domperidone Suspension contains sorbitol, methyl hydroxybenzoate and propyl hydroxybenzoate

This medicine contains 4000mg sorbitol in each 10ml dose, which is equivalent to 400mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you or your child have an

intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you or your child take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This medicine contains methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216), which may cause allergic reactions (possibly delayed).

3. How to take Domperidone Suspension

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

This product is not suitable for children under 12 years of age.

How long can I take domperidone suspension for?

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:** Take your medicine using the 5ml dosing syringe provided in the pack
- This syringe is marked in ml (millilitres) to help you measure out the correct amount of this medicine

Take your medicine 15 to 30 minutes before a meal.

The recommended dose is:

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

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

People with kidney problems

Your doctor may tell you to take a lower dose or to take the medicine less often.

How to use the oral syringe

1. Shake the bottle well making sure the cap is firmly on the bottle.
2. Remove the cap. Note: keep the cap nearby to close the bottle after each use.
3. Push the plastic adapter into the neck of the bottle. Note: the adapter must always stay in the bottle.
4. Take the syringe and check the plunger is fully down.
5. Keep the bottle upright and insert the oral syringe firmly into the plastic adapter.
6. Turn the whole bottle with the syringe upside down.
7. Slowly pull the plunger down fully so that the syringe fills with medicine. Push the plunger back up completely to expel any large air bubbles that may be trapped inside the oral syringe.
8. Then pull the plunger slowly back to the volume you need for your dose.
9. Turn the whole bottle with the syringe the right way up and take the syringe out of the bottle.

10. The dose of medicine can now be swallowed directly from the oral syringe. Please ensure that you are sitting upright and the plunger must be pushed slowly to allow you to swallow the dose.
11. Replace the child resistant cap after use, leaving the adapter in place.
12. To clean the oral syringe, take apart by removing the plunger completely. Pull straight out of the barrel. The barrel and plunger can be washed with soap and water, rinsed, and allowed to dry. Do not wash the oral syringe in the dishwasher.

If you take more Domperidone Suspension than you should:

- If you have used or taken too much Domperidone 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 (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 Suspension:

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, this medicine can have side effects, although not everybody gets them.

Stop taking Domperidone Suspension 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 .
- 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 Suspension 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 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.

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland:

HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Ireland. Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

5. How to store Domperidone Suspension

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

Do not take Domperidone Suspension after the expiry date (EXP) which is stated on the pack. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the bottle in the outer carton in order to protect from light.

Once the bottle is opened it should be used within 3 months.

Do not use this medicine if you notice visible signs of deterioration.

Do not 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 Suspension contains

1ml of Domperidone 1mg/ml Oral Suspension contains 1mg domperidone (the active ingredient). It also contains sorbitol (E420), microcrystalline cellulose (E460) and carmellose sodium, saccharin sodium (E954), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), polysorbate 20 (E432) and purified water.

What Domperidone Suspension looks like and contents of the pack

Each pack contains a 200 millilitre bottle of a white to off-white, opaque, oral suspension. It is supplied with a 5ml dosing syringe and bottle adapter and packed in an outer cardboard carton.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	Reference number
Domperidone 1mg/ml Oral Suspension	PL 29831/0522

This is a service provided by the Royal National Institute of Blind People.

For patients in the Republic of Ireland please call + 44 1978 661 261.

This leaflet was last revised in 01/2020

This medicinal product is authorised in the Member States of the EEA under the following names:

UK & Ireland: Domperidone 1mg/ml Oral Suspension