Package leaflet: Information for the user
Domperidone 10mg Film-Coated Tablets
Domperidone maleate

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, please ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you. 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 Domperidone Tablets are and what they are used for
2. What you need to know before you take Domperidone Tablets
3. How to take Domperidone Tablets
4. Possible side effects
5. How to store Domperidone Tablets
6. Contents of the pack and other information

1. What Domperidone Tablets are and what are they used for

The name of your medicine is Domperidone 10mg Film-Coated Tablets (called Domperidone Tablets in this leaflet). Domperidone is an anti-emetic which can stop you feeling sick. The active ingredient is domperidone maleate.

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

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

Do not take Domperidone Tablets
- 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.
- if you suffer from a tumour of the pituitary gland called prolactinoma
- if you have a blockage or tear in 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 Domperidone Tablets")

- if you have or may have a rare tumour of the adrenal gland (pheochromocytoma) because it could elevate your blood pressure.

If you are not sure, talk to your doctor or phamacist before taking Domperidone Tablets.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Domperidone Tablets
- 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 suffer from liver problems (liver function impairment or failure) (see "Do not take Domperidone Tablets")
- if you are taking a medicine called levodopa, see 'Other medicines and Domperidone Tablets'.

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.

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 Domperidone Tablets).

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.

Other medicines and Domperidone Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Do not take Domperidone Tablets 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 levodopa (a medicine used to treat the symptoms of Parkinson's disease), drugs to treat infection, heart problems or AIDS/HIV.

Domperidone Tablets and apomorphine:
Before you use Domperidone Tablets 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 Tablets are safe for you when you are taking any other medicines, including medicines obtained without prescription.

Taking Domperidone Tablets with food and drink
It is recommended to take Domperidone Tablets before meals, as when taken after meals the absorption of the medicine is slightly delayed.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. 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 tablets 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 Tablets contain lactose
- Lactose: If you have been told by your doctor that you have an intolerance to some sugars, check with your doctor before taking Domperidone Tablets.

- This medicine contains less than 1mmol sodium (23mg) per dosage unit, that is to say it is essentially ‘sodium-free’.

If you have any doubts about whether you should take this medicine then talk to your doctor.

3. How to take Domperidone Tablets

These tablets have been prescribed for you by a doctor. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The tablets should be swallowed whole with a sufficient quantity of liquid (e.g. one glass of water).

Duration of treatment:

Your doctor will decide how long you need to take this medicine.
Symptoms usually resolve with 3-4 days of taking this medicine. Do not take Domperidone Tablets for longer than 7 days without consulting your doctor.

Adults and adolescents <u>12 years of age and older</u> with a body weight of 35kg or more
The recommended dose is one tablet taken up to three times per day, if possible before meals. Do not take more than three tablets 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 Tablets than you should
- If you have used or taken too much Domperidone Tablets, contact your doctor, pharmacist or the poison centre immediately, in particular if a child has taken too much. Take this leaflet and any tablets you have left to show the doctor or pharmacist. 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 Tablets
Take your tablets as soon as you remember. If it is almost time for your next dose, wait until that is due and 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, this medicine can cause 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 irritablefeeling 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
- 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
- a worsening of restless leg syndrome in patients with Parkinson's disease.

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 Tablets

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

- Do not use this medicine after the expiry date printed on the package. The expiry date refers to the last day of that month.
- If you have any tablets that are out of date, please return them to your pharmacist for disposal.
- Do not store above 25°C. Store the tablets in the original package. Do not transfer Domperidone Tablets to another container.
- Do not throw away 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 Tablets contain
The active ingredient is domperidone maleate.
Each tablet contains 10mg domperidone as domperidone maleate.
Other ingredients in your tablets are lactose, pregelatinised maize starch, microcrystalline cellulose, sodium starch glycollate, magnesium stearate and Opadry white OY-S-28899 which consists of hypromellose, titanium dioxide (E171) and macrogol.

What Domperidone Tablets look like and contents of the pack
Domperidone 10mg Tablets are white, circular, film coated tablets marked DM on one face, 10 on the reverse.

Domperidone Tablets are available in blister packs or polyproylene/polyethylene containers with tamper evident closure in the following pack sizes:
10, 14, 20, 28, 30, 40, 42, 50, 56, 60, 70, 80, 84, 90, 98, 100 and 112. .
Not all pack sizes may be marketed.

Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.
Manufacturer: CP Pharmaceuticals Limited, 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 10mg Film-Coated Tablets	29831/0076

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

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