



PACKAGE LEAFLET: INFORMATION FOR THE USER

DOMPERIDONE TABLETS

10MG

TAJ PHARMA

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT DOMPERIDONE TABLETS ARE AND WHAT THEY ARE USED FOR

Domperidone Tablets contain domperidone as the active ingredient, which 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 35 kg or more).

2. BEFORE YOU TAKE DOMPERIDONE

Do Not take Domperidone Tablets if:

- You are allergic (hypersensitive) to domperidone or any of the other ingredients in the tablets.
- 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
- You have a blockage or tear in your intestines
- You have a tumour of the pituitary gland called a prolactinoma.
- have a disorder known as phenylketonuria (a metabolic disorder) orodispersible tablets should not be used as they contain aspartamine
- 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 tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Domperidone. Do this even if they have applied in the past.

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 medicinal product")\
- 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.

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.

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.

Other medicines and Domperidone tablets

Do not take Domperidone tablet 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)
- Hepatitis C (e.g., telaprevir)
- cancer (e.g., toremifene, vandetanib, vincamine)
- certain other medicines (e.g., bepridil, diphemanil, methadone)

Before you use Domperidone tablet 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 apomorphine leaflet

Tell your doctor or pharmacist if you are taking drugs to treat infection, heart problems or AIDS/HIV. It is important to ask your doctor or pharmacist if Domperidone tablet is safe for you when you are taking any other medicines, including medicines obtained without prescription.

Taking Domperidone Tablets with food and drink The tablets should be taken before meals.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking Domperidone tablets if:

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding. It is best not to take Domperidone tablets if you are breastfeeding. This is because small amount 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 feel sleepy, confused or have less control over your movements while taking Domperidone tablets. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Domperidone Tablets

The product contains lactose – if you know you have an intolerance to some sugars, tell your doctor before use.

Domperidone Tablets contain sodium **This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium free'**

3. HOW TO TAKE DOMPERIDONE TABLETS

Tablets exactly as your doctor has told you. You should check with your doctor or

pharmacist if you are not sure.
For **oral use only**.

The tablets must be swallowed with a glass of water.

Take the tablets 15 to 30 minutes before meals and, if needed, before you go to bed. Do not crush or chew them

Follow these instructions closely unless your doctor has advised you otherwise.

Duration of treatment:

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 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.

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 or someone else have used or taken too much Domperidone tablets, contact your doctor, pharmacist, nearest hospital casualty department or the poison centre immediately.

Always take any tablet left over with you, this leaflet and also the box, as this will allow easier identification of the tablets. In the events of overdose, symptomatic treatment could be implemented.

An ECG monitoring could be undertaken, because of the possibility of heart problem called prolonged QT interval.

Information for the doctor: close

observation of the patient and general supportive measures are recommended.

Anticholinergic anti-Parkinson medication may help to counteract the extrapyramidal disorders.

If you forget to take Domperidone Tablets

If you miss a dose, take your medicine as soon as you remember. If it is almost time for your next dose, wait until that is due and continue as usual.

Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Domperidone Tablets can have side effects, although not everybody gets them.

Uncommon (may affect up to 1 in 100 people):

- Involuntary movements of the face or arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm

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

- Seizures
- type of reaction that may occur soon after administration and is recognised by skin rash, itching, shortness of breath, and/or a swollen face
- A severe hypersensitivity reaction that may occur soon after administration that is characterised by hives, itching,

flushing, fainting, and difficulty breathing among other possible symptoms

- 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.

Stop treatment with Domperidone and contact your doctor immediately (in bold) if you experience any of the unwanted events described above.

Other unwanted effects that have been observed with Domperidone are listed below:

Common (may affect up to 1 in 10 people):

- Dry mouth

Uncommon (may affect up to 1 in 100 people):

- Anxiety
- Agitation
- Nervousness
- Loss of interest in sex or diminished interest in sex
- Headache
- Sleepiness
- Diarrhoea
- Rash
- Itchiness
- Hives
- Painful or tender breasts
- Milk discharge from breasts
- A general feeling of weakness
- Feeling dizzy



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

- Upward movement of the eyes
- Stopped menstrual periods in women
- Enlarged breasts in men
- Inability to urinate
- Changes in certain laboratory test results
- Restless legs syndrome (uncomfortable feeling, with an irresistible urge to move your legs, and sometimes arms and other parts of your body)

Some patients who have used Domperidone for conditions and dosages requiring medical oversight 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 or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE DOMPERIDONE

Keep out of the reach and sight of children. Do not store above 25°C. Store in the original package.

Do not use the tablets after the expiry date is stated on the label. 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.

6. FURTHER INFORMATION

What Domperidone Tablets contain The active substance is domperidone maleate, 10mg per tablet.

Each uncoated tablet contains:

Domperidone maleate equivalent to domperidone	10mg
Excipients	q.s.

What Domperidone Tablets looks like and contents of the pack

PVC/PVDC/Al blisters.

Pack sizes: Blisters: 7, 14, 28, 30, 50, 90, 100 and 500mg modified-release tablets.

Not all pack sizes may be marketed.

7. MANUFACTURED IN INDIA BY:

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