

PACKAGE LEAFLET: INFORMATION FOR THE USER

DISMOTIL TABLETS 10MG [Domperidone Maleate]

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

What is in this leaflet:

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

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

The active ingredient in Dismotil Tablets is domperidone.

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

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

Do not take Dismotil if:

- you are hypersensitive (allergic) to domperidone or any of the other ingredients of Dismotil Tablets (listed in section 6)
- you have a disease or tumour of the pituitary gland (prolactinoma)
- you have severe tummy cramps or pain, or persistent black stools or blood in the stool
- you have a moderate or severe liver disease
- your ECG (electrocardiogram) shows a heart problem called "prolonged QT corrected interval"
- 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)
- you have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood
- you are taking certain medicines (see Other medicines and Dismotil Tablets).

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 Dismotil Tablets”)
- 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. The 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 Dismotil).

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

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.

Dismotil Tablets are not suitable for use in children weighing less than 35kg. *If Dismotil Tablets are for children, ask your doctor for the children’s formulation.*

Other medicines and Dismotil Tablets

Do not take Dismotil 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 (e.g. 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.

Tell your doctor if you are taking:

-Bromocriptine which is used to treat patients with conditions which result from having high levels of the hormone prolactin in the blood

- Opioid analgesics which are strong pain killers (e.g. morphine, codeine, methadone, pethidine)

- Anti-muscarinics which are used for disorders of the gut and digestive system (e.g. atropine, mebeverine, hyoscine, propantheline).

It is important to ask your doctor or pharmacist if Dismotil Tablets are safe for you when you are taking any other medicines, including medicines obtained without a prescription.

Pregnancy:

It is not known whether it is safe to take Dismotil Tablets when pregnant. If you are pregnant or think you might be pregnant ask your doctor or pharmacist for advice before taking any medicine.

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:

At normal doses, Dismotil does not affect your ability to drive or use machines. If you notice symptoms of drowsiness, confusion, impaired awareness and lack of co-ordination do not drive or operate machines.

Dismotil Tablets contain lactose:

The tablets contain lactose.

They may not be suitable for patients with lactose intolerance (inability to digest lactose, which is sugar found in milk and milk products), galactosaemia or glucose/galactose malabsorption (inability to digest carbohydrates and sugars which are found in many foods including starches, milk and milk products).

If you have been told by your doctor that you have an intolerance to some sugars, you should talk to your doctor before taking these tablets.

3. How to take Dismotil Tablets

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

Duration of treatment:

Symptoms usually resolve within 3-4 days of taking this medicine. Do not take Dismotil 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:

Dismotil Tablets should be taken with a glass of water, by mouth.

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.

If you have kidney problems your doctor may tell you to take a lower dose, less often.

Dismotil Tablets are unsuitable for use in children weighing less than 35kg.

If you take more Dismotil Tablets than you should:

If you have used or taken too much Dismotil, contact your doctor, pharmacist or the poison centre immediately, in particular if a child has taken too much. In the event of an overdose, symptomatic treatment could be implemented. An ECG monitoring could be undertaken, because of the possibility of a heart problem called prolonged QT interval.

If you have taken too much Dismotil you may also experience sleepiness, confusion, uncontrolled movements, such as irregular eye movements or abnormal posture, such as a twisted neck.

If you forget to take Dismotil Tablets:

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.

How long can I take this medicine for?

You should not take this medicine for longer than 7 days without talking to your doctor.

4. Possible side effects

Like all medicines, Dismotil Tablets can cause side effects, although not everybody gets them.

Allergic reactions:

If you have any of these symptoms stop taking Dismotil and see your doctor immediately:

Very rare (less than 1 in 10,000 people):

- Allergic reactions such as itching, shortness of breath, wheezing and/or a swollen face
- Hives or skin rash.

If you experience any of the following contact your doctor immediately:

Changes in heart rhythm, heart thumping or palpitations, chest pain, shortness of breath, loss of consciousness or a feeling of light headedness.

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 in adults and children.

You may experience the other following side effects:

Very rare (less than 1 in 10,000 people):

- Mild intestinal cramps, diarrhoea – this is usually only for a short time and goes away by itself. If this problematic speak to your doctor or pharmacist
- Uncontrolled movements, a feeling of inner restlessness such as irregular eye movements, and abnormal posture such as a twisted neck, trembling and muscle stiffness have been observed but these disappear as soon as Domperidone is stopped.
- There have been reports of reduced sex drive.

Rare (between 1 in 1,000 and 1 in 10,000 patients):

- Some people develop swollen or sore breasts and/or milk flow and rarely in women menstrual periods may be irregular or stop.

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

By reporting side effects you can help provide more information on the safety of this medicine.

5.How to store Dismotil Tablets

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not use Dismotil Tablets after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not use Dismotil Tablets if you notice visible signs of deterioration.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6.Contents of the pack and other information

What Dismotil Tablets contains

The active substance is Domperidone Maleate BP/Ph Eur.

The other ingredients are:

Lactose/Lactose monohydrate

Maize starch

Microcrystalline cellulose (Avicel PH 102)

Povidone (K-30)

Sodium Lauryl Sulphate/Sodium Lauril Sulfate

Colloidal Anhydrous Silica

Magnesium Stearate (Vegetable).

What Dismotil Tablets look like and contents of the pack

Description: White, round, biconvex tablets marked “Dm 10” on one side and plain on the other side.

Contents of the pack:

10 tablets in a blister, 3 blisters in a carton.

10 tablets in a blister, 10 blisters in a carton.

Marketing Authorisation Holder

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