

MOTILIUM 10 mg FILM-COATED TABLETS

Domperidone

PATIENT INFORMATION LEAFLET

▼ 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.

- 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect

In this leaflet:

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

1. WHAT MOTILIUM IS AND WHAT IT IS USED FOR

The name of your medicine is Motilium 10mg Film-Coated Tablets (called Motilium in this leaflet). Motilium contains a medicine called domperidone. This belongs to a group of medicines called 'dopamine antagonists'.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MOTILIUM

Do not take Motilium tablets if:

- You are allergic (hypersensitive) to domperidone or any of the other ingredients of Motilium 10mg Film-Coated Tablets (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.
- You have a tumour of the pituitary gland (prolactinoma)
- You have a blockage or tear in your intestines
- 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 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 Motilium")

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

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

Motilium 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 Motilium 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 "Other medicines and Motilium").

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

While taking Motilium, contact your doctor if you experience heart rhythm disorders such as palpitations, trouble breathing, loss of consciousness. Treatment with Motilium should be stopped.

Other medicines and Motilium

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

Do not take Motilium 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 drugs to treat infection, heart problems or AIDS/HIV.

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

Taking Motilium with food and drink

It is recommended to take Motilium 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 Motilium if:

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding. It is best not to take Motilium if you are breast-feeding.

Small amounts of Motilium may not be detected in breast-milk. Motilium may cause unwanted side effects affecting the heart in a breast-fed baby. Motilium 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:

Motilium does not affect your ability to drive or use machines.

Important information about some of the ingredients of Motilium tablets

This medicine contains lactose. If you have been told that you cannot digest or tolerate some sugars, talk to your doctor before taking Motilium.

3. HOW TO TAKE MOTILIUM

Follow these instructions closely unless your doctor has advised you otherwise. You should 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 within 3-4 days of taking this medicine. Do not take Motilium 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.

The usual dose is:

- **Adults and adolescents 12 years of age and older with a body weight of 35kg 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 35kg**

Motilium tablets are not suitable for children weighing less than 35kg.

If Motilium is for a child, ask your doctor for the children's formulation

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 Motilium than you should:

- If you have used or taken too many Motilium tablets contact your doctor, pharmacist or the poisons centre at your nearest hospital casualty department 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 Motilium:

- If you forget to take Motilium, take it as soon as you remember.
- However if it is almost time for the 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, Motilium can have side effects, although not everybody gets them.

Stop taking Motilium 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 Motilium.
- 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 Motilium.
- 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 1,00 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. Motilium 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. Motilium should be used at the lowest effective dose in adults and children.
- 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 Motilium 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, 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 MOTILIUM

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not take Motilium Tablets after the expiry date stated on the pack.
- Ask your pharmacist how to dispose of medicines you no longer need. Do not dispose of medicines by flushing down a toilet or sink, or by throwing them out with your normal household rubbish. This will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Motilium 10mg Film-Coated Tablets contain

Each Motilium Tablet contains 10mg of domperidone (the active ingredient). It also contains lactose, maize starch, microcrystalline cellulose, hypromellose, pregelatinised starch, povidone, propylene glycol, magnesium stearate, silica colloidal hydrated and polysorbate 20.

What Motilium 10mg Film-Coated Tablets look like and contents of the pack

Each pack contains 30 or 100 white to cream coloured, film-coated tablets with Motilium stamped on one side.

Marketing Authorisation Holder is:

Zentiva One Onslow Street, Guildford, Surrey, GU1 4YS, UK

Manufacturer is:

Fawdon Manufacturing Centre, Edgefield Avenue, Fawdon, Newcastle-upon-Tyne, Tyne & Wear, NE3 3TT.

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