

## PATIENT INFORMATION LEAFLET

### Motilium® 1 mg/ml oral suspension

(domperidone)

**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 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 1 mg/ml oral suspension (called Motilium 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 weighing 35 kg or more).

#### 2. What you need to know before you take Motilium

##### Do not take Motilium 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.
- You have a tumour of the pituitary gland (prolactinoma).
- You have or may have a rare tumour of the adrenal gland (pheochromocytoma) because it could elevate your blood pressure.
- 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 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.

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.

#### Adolescents weighing less than 35 kg and children

Motilium 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 Motilium

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, AIDS/HIV or Parkinson’s disease.

Tell your doctor if you are taking antacids or other medicines that reduce stomach acid (such as cimetidine or sodium bicarbonate). These medicines can be taken if you are also taking Motilium but they should not be taken at the same time as they may affect how well Motilium works. Medicines that reduce stomach acid should be taken after a meal.

#### Motilium and apomorphine

Before you use Motilium 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 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 have been 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 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.

#### Motilium contains sorbitol, methylhydroxybenzoate and propyl parahydroxybenzoate

- Each 5 ml contains 2.275 g of sorbitol. If you have been told that you cannot digest or tolerate some sugars, talk to your doctor before taking Motilium.
- Each 5 ml contains 9 mg of methylhydroxybenzoate (E218) and 1 mg of propylhydroxybenzoate (E216). These substances may cause allergic reactions (possibly delayed).

#### 3. How to take Motilium

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

- Take this medicine by mouth.
- **Adults and adolescents 12 years of age and older and with a body weight of 35 kg or more:** take your medicine using the plastic measuring cup provided with Motilium. This cup is marked in ml (millilitres) to help you measure out the correct amount of this medicine.

- This product is not suitable for children under 12 years of age and older with a body weight of less than 35 kg.
- Take your medicine 15 to 30 minutes before a meal.

The usual dose is:

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

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

- If you have used or taken too much Motilium, 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 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, this medicine 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. 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 100 people)

- Lowering of sexual drive (libido) in men
- Feeling anxious
- Feeling agitated or irritable
- Feeling more nervous than usual
- Feeling drowsy
- Headaches
- Diarrhoea
- Itchy skin. You may also have a rash

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- 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 adolescents 12 years of age and older.
- Abnormal eye movements
- Feeling the urge to move your legs, arms or other parts of your body (restless legs syndrome). These symptoms may become worse in patients suffering from Parkinson's disease
- 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.

**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](http://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 Motilium**

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the carton and the bottle label after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- If your medicine shows any signs of deterioration or discolouration, consult your doctor or pharmacist for advice. If damaged, please tell your doctor or pharmacist.
- 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 Motilium contains**

The active ingredient in Motilium is domperidone. Each ml of the suspension contains 1 mg domperidone.

Also contains sodium saccharin (E954), microcrystalline cellulose (E460), sodium carboxymethylcellulose (E466), sorbitol solution (non-crystallising) E420, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), polysorbate 20, sodium hydroxide and purified water.

**What Motilium looks like and contents of the pack**

Motilium is a white homogenous oral suspension.

Your medicine is available in a white plastic bottle with a child resistant screw cap containing 200 ml of the liquid suspension. Also includes a 20 ml/40 ml measuring cup.

Manufactured by: TOWA Pharmaceutical Europe, S.L. c/ de Sant Marti, 75-97 08107 Martorelles, Barcelona, Spain or Esteve Pharmaceuticals, S.A., C/Sant Marti, 75-97. Pol. Industrial La Roca, 08107 Martorelles, Barcelona, Spain. Procured from within the EU. Product Licence Holder: Quadrant Pharmaceuticals Limited, Lynstock House, Lynstock Way, Lostock, Bolton, BL6 4SA. Repackaged by: Maxearn Limited, Unit 29, Oakhill Trading Estate, Devonshire Road, Worsley, Manchester, M28 3PT.

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**Blind or partially sighted?**

**Is this leaflet hard to see or read?**

**Contact Quadrant Pharmaceuticals**

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