

Package leaflet: Information for the user

MOTILIUM® 10 mg film-coated tablets

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 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
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1. What MOTILIUM is and what it is used for

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. What you need to know before you take

MOTILIUM Do not take MOTILIUM if you:

- are allergic (hypersensitive) to domperidone or any of the other ingredients of MOTILIUM
- have stomach bleeding or if you regularly have severe abdominal pain or persistent black stools (poo)
- have a blocked or perforated gut
- have a tumour of the pituitary gland (prolactinoma)
- if you have or may have a rare tumour of the adrenal gland (pheochromocytoma) because it could elevate your blood pressure
- have a moderate or severe liver disease
- have an ECG (electrocardiogram) that shows a heart problem called “prolonged QT interval”
- have or had a problem where your heart cannot pump the blood around your body as well as it should (condition called heart failure)
- have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood
- are taking certain medicines (see “Taking other medicines”).

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”)
- 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 in those taking doses higher than 30 mg 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 “Taking other medicines”).

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.

Children 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.

Taking other medicines

Do not take MOTILIUM if you are taking medicine to treat:

- fungal infections, e.g., pentamidine or azole anti-fungals, specifically itraconazole, oral ketoconazole, fluconazole, posaconazole or voriconazole
- bacterial infections, specifically erythromycin, clarithromycin, telithromycin, levofloxacin, moxifloxacin, spiramycin (these are antibiotics)
- heart problems or high blood pressure (e.g., amiodarone, dronedarone, ibutilide, quinidine, disopyramide dofetilide, sotalol, hydroquinidine)
- 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, lumefantrine)
- AIDS/HIV such as ritonavir or saquinavir (protease inhibitors)
- Hepatitis C (e.g., telaprevir)
- cancer (e.g., toremifene, vandetanib, vincamine)

Do not take MOTILIUM if you are taking certain other medicines (e.g., bepridil, diphemanil, methadone).

Tell your doctor or pharmacist if you are taking drugs to treat infection, heart problems, AIDS/HIV or Parkinson’s disease.

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

Take MOTILIUM before meals, as when taken after meals, the absorption of the medicine is slightly delayed.

Pregnancy

It is not known whether the use of MOTILIUM is harmful during pregnancy. If you are pregnant

or think you may be you should inform your doctor who will decide if you can take MOTILIUM.

Breast-feeding

Small amounts of domperidone 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 doctor considers this clearly necessary. Ask your doctor for advice before taking this medicine.

Driving and using machines

Some patients have reported feeling dizzy or sleepy after taking MOTILIUM. Do not drive or use machinery while taking MOTILIUM until you know how MOTILIUM affects you.

Important information about some of the ingredients of MOTILIUM:

- The film-coated tablets contain lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take MOTILIUM

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

Take Motilium before meals, as when taken after meals, the absorption of the medicine is slightly delayed.

Duration of treatment

Symptoms usually resolve with 3-4 days of taking this medicine. Do not take MOTILIUM for longer than 7 days without consulting your doctor.

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

Tablets

The usual dose is one tablet taken up to three times per day, if possible before meals. Take the tablet with some water or other liquid. Do not chew the tablet. Do not take more than three tablets per day.

If you take more MOTILIUM than you should

If you have used or taken too much MOTILIUM, contact your doctor, pharmacist or the poison centre immediately. 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".

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 MOTILIUM

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.

4. Possible side effects

Like all medicines, this medicine can cause 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
- A 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 MOTILIUM and contact your doctor immediately if you experience any of the unwanted events described above.

Other unwanted effects that have been observed with MOTILIUM 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 MOTILIUM 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly *via* ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal.

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

5. How to store MOTILIUM

- Keep the medicine out of the reach and sight of children.
- Do not use MOTILIUM after the expiry date which is stated on the pack. The expiry date “exp.” refers to the last day of the month shown where the first two figures indicate the month, the next the year.
- Do not store above 30°C. Do not refrigerate or freeze. Keep container in the outer carton to protect from light.

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. Contents of the pack and other information

What MOTILIUM contains

The active substance is domperidone.

The other ingredients are:

- Lactose, maize starch, microcrystalline cellulose, potato starch, polyvidone, magnesium stearate, vegetable oil, sodium lauryl sulphate, hypromellose

What MOTILIUM looks like and contents of the pack

- The tablets are available in a blister pack containing 30 tablets.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

Johnson & Johnson Hellas Consumer AE
Aegialias & Epidavrou 4, Maroussi, 15125, Athens, Greece

Manufacturer

Janssen-Cilag, Domain de Maigremont, 27100 Val De Reuil, France

Marketing authorisation numbers

Film-coated tablets (domperidone): MA1471/00501

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