

Yellow highlighted text for prescription product, turquoise highlighted text - alternative wording for the non-prescription product.

PACKAGE LEAFLET: INFORMATION FOR THE USER

MOTILIUM[®]

- **10mg suppositories** (10 mg domperidone per suppository)
- **30mg suppositories** (30 mg domperidone per suppository)

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 you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 14 days.
- If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What MOTILIUM is and what it is used for
2. Before you use MOTILIUM.
3. How to use MOTILIUM.
4. Possible side effects.
5. How to store MOTILIUM.
6. Further information.

1. What MOTILIUM is and what it is used for

MOTILIUM is a medicine that increases the movements or contractions of the stomach or bowel.

Motilium 10 and 30 mg suppositories are used in children to treat nausea (feeling sick) and vomiting (being sick).

2. Before you use MOTILIUM

Do not use 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).
- Taking certain medicines that slow down the metabolism (the breaking down) of other medicines in the body and can also affect your heart rhythm such as ketoconazole, fluconazole or voriconazole, which are

Yellow highlighted text for prescription product, turquoise highlighted text - alternative wording for the non-prescription product.

used to treat fungal infections; the antibiotics erythromycin, clarithromycin or telithromycin; or amiodarone, a heart medicine.

- If you have or have had liver disease.

Take special care with MOTILIUM

- If you have kidney problems, follow your doctor's instructions carefully/consult your doctor before taking this medicine.
- If you are also taking other medicines. Please also read "Using other medicines" section.

This medicinal product is not suitable for children weighing less than 5 kg

Use in young children

When Motilium is used in young children, there is a small chance they might develop abnormal muscle movements or tremor (shaking). It is important to strictly keep to the dosage as prescribed by your doctor or as instructed in this leaflet.

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

Duration of use

When Motilium is not prescribed to you by a doctor, you should not use it for longer than 14 days. Contact your doctor if your symptoms persist after 14 days.

Do not take Motilium for longer than 14 days unless prescribed by your doctor.

Using other medicines

Do not take MOTILIUM if you are taking oral ketoconazole (a medicine for fungal infections), or oral erythromycin (an antibiotic) or certain medicines that slow the metabolism (the breaking down) of other medicines in the body and can also affect your heart rhythm.

Tell your doctor or pharmacist if you are taking drugs to treat infection, heart problems or AIDS/HIV, the antidepressant nefazadone, or aprepitant, a medicine used to reduce nausea associated with cancer chemotherapy.

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

Taking MOTILIUM with food and drink

The absorption of MOTILIUM Suppositories is not affected by food or drink.

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 MOTILIUM have been detected in breast milk. Therefore, the use of MOTILIUM is not recommended for nursing mothers.

Always ask your doctor or pharmacist for advice before using any medicine.

Yellow highlighted text for prescription product, turquoise highlighted text - alternative wording for the non-prescription product.

Driving and using machines

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

Important information about some of the ingredients of MOTILIUM:

- MOTILIUM suppositories contain an ingredient called butylated hydroxyanisole which can irritate eyes, skin and the lining of the mouth and nose (mucous membranes). If you think you have such a reaction please tell your doctor.

3. How to use MOTILIUM

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

If you are unsure of anything, consult your doctor or pharmacist. If you do not feel better after 2 weeks, make sure you consult your doctor.

Children 12 years of age or less with a body weight of 5kg or more

- Your doctor will explain to you exactly how much of this medicine to give to the child, and how often, because the dose is dependent on the weight of the child.
- The normal dose for a child weighing 5 to 15kg is one 10mg suppository twice daily.
- The normal dose for a child weighing more than 15kg is one 30mg suppository twice daily.
- MOTILIUM suppositories are not suitable for children weighing less than 5 kg.

Inserting the suppositories

- First wash your hands.
- The suppository should be moistened and then inserted into the bottom as far as possible.
- Once this has been done tense your muscles to prevent the suppository coming out.

If you take more MOTILIUM than you should

In the event of an overdose, agitation, altered state of awareness or trance, seizure, confusion, sleepiness, uncontrolled movements, such as irregular eye movements or abnormal posture, such as twisted neck can occur. When you have used or taken too much MOTILIUM, contact your doctor, pharmacist or the poison center immediately, in particular when a child has taken too much, and also if you/they have swallowed the suppository.

Information for the doctor: close observation of the patient, gastric lavage, administration of activated charcoal and general supportive measures are recommended. Anticholinergic anti-Parkinson medication may help to counteract the extrapyramidal reactions.

If you forget to take MOTILIUM

If you miss a dose, take the next dose as soon as possible. However, if it is almost time to take the next dose, forget about the missed dose and continue as normal. Do not take a double dose to make up for a missed dose.

Yellow highlighted text for prescription product, turquoise highlighted text - alternative wording for the non-prescription product.

4. Possible side effects

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

Very rare (reported by fewer than 1 in 10,000 patients):

- Seizures
- Involuntary movements of the face or arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm
- A type of reaction that may occur soon after administration and is recognized by skin rash, itching, shortness of breath, and/or a swollen face
- A severe hypersensitivity reaction that may occur soon after administration that is characterized by hives, itching, flushing, fainting, and difficulty breathing among other possible symptoms
- Heart rhythm disorder
- Unexpected death resulting from an abrupt loss of heart function in a person who may or may not have known heart disease

Stop treatment with domperidone 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 (reported by at least 1 in 100 patients but fewer than 1 in 10 patients):

- Dry mouth

Uncommon (reported by at least 1 in 1000 patients but fewer than 1 in 100 patients):

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

Rare-(reported by at least 1 in 10,000 patients but fewer than 1 in 1000 patients):

- Stopped menstrual periods in women

Very Rare (reported by fewer than 1 in 10,000 patients):

- Hives
- Agitation
- Nervousness
- Inability to urinate
- Changes in certain laboratory test results.

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.

Yellow highlighted text for prescription product, turquoise highlighted text - alternative wording for the non-prescription product.

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

If any of these unwanted effects occur, consult your doctor or pharmacist immediately.

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.

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 MOTILIUM above 25°C.
- Store the suppositories in a dry place.

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 MOTILIUM contains

The active substance is domperidone.

The other ingredients are:

Tartaric acid, macrogol 4000, macrogol 1000, macrogol 400, butyl hydroxyanisol.

What MOTILIUM looks like and contents of the pack

To be added nationally

Marketing authorisation holder and manufacturer

Registration holder

To be added nationally

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

Manufacturer

Cilag AG, Hochstrasse 201, CH-8205 Schaffhausen

Or for 30 mg suppositories only:

Lusomedicamenta Sociedade Técnica Farmacêutica, S.A.

Queluz,
Portugal

Yellow highlighted text for prescription product, turquoise highlighted text - alternative wording for the non-prescription product.

Registration number

To be added nationally

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
Austria	Motilium
Belgium	Motilium
Denmark	Motilium
Ireland	Motilium
Luxembourg	Motilium
Netherlands	Motilium

Latest update of this package insert: April 2012

The date of approval of this package insert is mm/yyyy