

PACKAGE INSERT LEAFLET: INFORMATION FOR THE USER

MOTILIUM

1 mg/ml of oral suspension
(1 mg of domperidone per 1 ml of suspension)

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 symptoms are the same as yours.
- If you get any side effects not mentioned in section 4, including any possible side effects not listed in this leaflet, check with your doctor or pharmacist.

What is in this leaflet:

1. What Motilium is and what it is used for
2. Warnings and precautions
3. How to take Motilium
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. WHAT MOTILIUM IS AND WHAT IS IT USED FOR

Motilium suspension is used to treat nausea and vomiting in adults and adolescents (12 years and older, weighing at least 35 kg).

2. WARNINGS AND PRECAUTIONS

Do not take this medicine:

- If you have an allergy to one of the ingredients of this medicine. These ingredients are listed in section 6.
- If you have a stomach bleeding or regularly have serious abdominal pain or persistent black stools;
- If you have a blocked or perforated intestine;
- If you have a tumour of the hypophysis (prolactinoma);
- If you have a moderate or serious liver disease;
- If your ECG (electrocardiogram or echogram for the heart) indicates that you have a heart problem called “corrected QT interval prolongation”;
- If you have or had a problem causing your heart to be unable to pump enough blood through your body (a condition called heart failure);
- If you have a problem causing low potassium or magnesium levels or high potassium levels in the blood;
- If you use certain medicines (see "Other medicines and Motilium").

When to take special care with Motilium

Talk to your doctor before taking this medicine if you:

- have liver problems (liver function disorders or liver failure) (see “Warnings and precautions”);

- have kidney problems (kidney function disorders or kidney failure). Ask your doctor for advice in case of long-term treatment, because you will probably have to use a lower dose or use this medicine less often. Your doctor may also consider a regular examination necessary.

Domperidone may be associated with a higher risk of cardiac arrhythmias and cardiac arrest. Chances of this are greater in people over 60 years of age or in people taking a dose higher than 30 mg per day. Chances of this are also greater if domperidone is used together with certain other medicines. Tell your doctor or pharmacist if you use medicines against infections (fungal infections or bacterial infections) and/or if you have heart problems or AIDS/HIV (see the section “Other medicines and Motilium”).

The lowest effective dose of Motilium must be used.

Contact your doctor if you experience cardiac arrhythmias such as palpitations, breathing difficulties or loss of consciousness when using Motilium. The treatment with Motilium must be discontinued.

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

Do you use other medicines in addition to Motilium or did you do so a short time ago or is there a possibility that you will use other medicines in the near future. Tell your doctor or pharmacist.

Do not use Motilium if you use medicines to treat:

- fungal infections, such as pentamidine or azole antifungal medication, especially itraconazole, oral ketoconazole, fluconazole, posaconazole or voriconazole;
- bacterial infections, particularly erythromycin, clarithromycin, telithromycin, levofloxacin, moxifloxacin, spiramycin (these are antibiotics);
- heart problems or high blood pressure (e.g. amiodarone, dronedarone, ibutilide, kinidine, disopyramide, dofetilide, sotalol, hydrokinidine);
- psychosis (e.g. haloperidol, pimozide, sertindol);
- depression (e.g. citalopram, escitalopram);
- gastrointestinal disorders (e.g. cisapride, dolasetron, prucalopride);
- allergy (e.g. mequitazine, mizolastine);
- malaria (particularly halofantrine, lumefantrine);
- AIDS/HIV such as e.g. ritonavir or saquinavir (these are protease inhibitors);
- hepatitis C (e.g. telaprevir);
- cancer (e.g. toremifene, vandetanib, vincamine).

No not take Motilium if you use certain other medicines (e.g. bepridil, difemanil, methadone).

Tell your doctor or pharmacist if you use medicines against infections, heart problems, AIDS/HIV or Parkinson's disease.

Motilium and apomorphine

Before you use Motilium and apomorphine, your doctor will check if you tolerate both medicines in case of concomitant use. Ask your doctor or specialist for personal advice. Consult the package insert leaflet of apomorphine.

It is important to ask your doctor or pharmacist if Motilium is safe for you if you use other medicines, including OTC medicines.

Motilium with food and drink

It is recommended to take Motilium before meals. If it is taken after the meal the absorption of the medicine is somewhat delayed.

Pregnancy

It is not known if the use of Motilium is harmful during pregnancy.

If you are pregnant, think you may be pregnant, want to become pregnant or are breastfeeding, then talk to your doctor or pharmacist before taking this medicine. Your doctor will decide whether you should use this medicine.

Breast feeding

Small amounts of Motilium have been found in breast milk. Motilium may cause adverse reactions which influence the heart of a breast-fed baby. Motilium must be used during breastfeeding only if your doctor considers it strictly necessary. Ask your doctor for advice before you take this medicine.

Driving and using machines

Some patients have reported dizziness or drowsiness after taking Motilium. Do not drive vehicles while taking Motilium until you know how it affects you.

What Motilium contains

- Motilium suspension contains less than 1 mmol of sodium (23 mg) in each ml, that is to say, essentially 'sodium-free'.
- Motilium suspension contains 455 mg sorbitol (E420) in each ml, which may cause gastrointestinal discomfort and mild laxative effect. Sorbitol is also a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take this medicine.
- Motilium suspension also contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). These substances may cause (possibly delayed) allergic reactions, and, in exceptional cases, bronchospasm.

3. HOW TO TAKE MOTILIUM

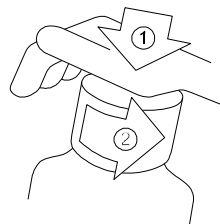
Follow these instructions carefully, unless your doctor prescribes you otherwise. You should check with your doctor or pharmacist if you are not sure.

It is recommended to take Motilium before meals. If it is taken after the meal the absorption of the medicine is somewhat delayed.

Duration of treatment

The symptoms usually disappear within 3-4 days after you start using this medicine. Do not use Motilium for more than 7 days without talking to your doctor.

The bottle is protected by a child-proof cap. To open the bottle, push the plastic screw cap down and turn it counter-clockwise. Keep turning downwards as shown below.



Mix the contents of the bottle well by tilting the bottle, in order to prevent foam formation.

Adults and young people from 12 years of age and with a body weight of 35 kg or more

- This medicine comes with a measuring cup. This measuring cup has three marks: 2.5 ml, 5 ml and 10 ml (the measuring cup contains for example 10 ml of oral suspension if it is filled up to the top mark).
- Use the measuring cup supplied on the cap of the bottle. Make sure that the part with the scale division (the part that can hold less liquid) is at the top. That's the part you have to fill. If the arrow on the side of the measuring cup points upwards, the right part is at the top.



- Measure the required quantity in the measuring cup.
- Do not dilute Motilium and do not mix it with other liquids.
- The recommended dose is 10 mg, maximum three times per day, if possible before meals. Do not take more than 30 mg per day (this equals 3 measuring cups filled to the top mark).
- Clean the measuring cup after use.

If you take more Motilium than you should

If you have taken more Motilium than you should, immediately contact your doctor, pharmacist or the Poison Control Centre. In case of an overdose, a symptomatic treatment may be initiated. Because of the chance of a heart problem called QT interval prolongation, an ECG check may be performed.

Information for the doctor: careful observation of the patient and general supporting measures are recommended. Anticholinergic anti-Parkinson's medicines may help to fight the extrapyramidal disorders.

If you forget to take this medicinal product

Take the medicinal product as soon as you remember. However, if it is nearly time for the following dose, then skip the forgotten dose and continue the normal scheme. 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 (reported by less than 1 in 100 patients):

- Involuntary movements of the face, arms or legs, excessive trembling, excessive muscle rigidity or muscle spasms.

Not known (cannot be determined with the available data)

- Convulsions;
- A kind of reaction which may occur soon after administration and which can be recognized by rash, itching, shortness of breath, and/or a swollen face;

- A serious oversensitivity reaction which may occur soon after administration and can be recognized by hives, itching, hot flushes, fainting, breathing difficulties, and other possible symptoms;
- Disorders of the heart and the blood vessels (the cardiovascular system): cardiac arrhythmias (fast or irregular heartbeat) have been reported. Should this occur, the treatment must be stopped immediately. Domperidone may be associated with a higher risk of cardiac arrhythmias and cardiac arrest. Chances of this may be greater in people over 60 years of age or in people taking a dose higher than 30 mg per day. The lowest effective dose of domperidone must be used.

Stop the Motilium treatment and immediately contact your doctor immediately if you notice the adverse reactions described above.

Other adverse reactions observed with Motilium are listed below:

Common (reported by at least 1 in 100 patients but by less than 1 in 10 patients):

- Dry mouth.

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

- Anxiety;
- Restlessness;
- Nervousness;
- Loss of libido or decreased interest in sex;
- Headache;
- Drowsiness;
- Diarrhoea;
- Rash;
- Itching;
- Hives;
- Painful or sensitive breasts;
- Lactation from the breasts;
- General feeling of weakness;
- Feeling dizzy.

Not known (cannot be determined with the available data):

- Eyes turning upwards;
- No menstruation in women;
- Enlarged breasts in men;
- Inability to urinate;
- Changes in certain laboratory test results;
- “Restless leg” syndrome (discomfort, with an irresistible urge to move the legs, and sometimes the arms and other body parts).

Some patients who have used Motilium for disorders and in doses which require medical supervision experienced the following adverse reactions: restlessness, swollen or enlarged breasts, unusual secretion from the breasts, irregular menstruation in women, breastfeeding difficulties, depression, oversensitivity.

Reporting of side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. By reporting side effects, you can help us to obtain more information on the safety of a medicine.

5. HOW TO STORE THIS MEDICINE

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the pack after the letters 'EXP'. 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.
- Store at temperature not exceeding 30 ° C
- Motilium suspension must not be used longer than 3 months after the first opening of the bottle.

Medicines should not be disposed of via wastewater or household waste Ask your pharmacist what to do with medicines that you are no longer using. 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 in this medicinal product are: sorbitol 70% ordinary, non-crystallized solution (E420), microcrystalline cellulose, sodium carboxyl methyl cellulose, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium saccharin, polysorbate 20, sodium hydroxide, and purified water.

What Motilium looks like and contents of the pack

- The oral suspension is available in a 100 ml bottle and a 200 ml bottle, delivered with a measuring cup of 10 ml (with marks for 2.5 ml, 5 ml, and 10 ml).

Marketing authorisation holder:

Janssen-Cilag NV Antwerpseweg 15-17 2340 Beerse, Belgium

Manufacturer:

Janssen pharmaceutica NV- Turnhoutseweg 30-B- 2340 Beerse-Belgium

To contact us, go to www.janssen.com/contact-us

This package insert was last approved in 29 October 2020

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists