

Package leaflet: Information for the user

Motilium®

10 mg Film Coated Tablets

domperidone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

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1. What Motilium 10 mg Tablets are 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 35kg or more.

2. What you need to know before you take Motilium 10 mg Tablets

Do not take Motilium 10 mg Tablets if you:

- are allergic (hypersensitive) to domperidone or any of the other ingredients of Motilium 10 mg Tablets
- have stomach bleeding or if you regularly have severe abdominal pain or persistent black stools
- have a blocked or perforated gut
- have a tumour of the pituitary gland (prolactinoma)
- 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 10 mg Tablets")
- 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.
- are older than 60 years of age.

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").

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

While taking domperidone, contact your doctor if you experience heart rhythm disorders such as palpitations, trouble breathing, loss of consciousness.

Treatment with domperidone should be stopped.

Children and adolescents

Do not give this medicinal product to children under 12 years of age. Do not give this medicinal product to adolescents weighing less than 35 kg.

Other medicines and Motilium 10 mg Tablets

Do not take Motilium 10 mg Tablets if you are taking medicine to treat:

- fungal infections e.g. pentamide or azole anti-fungals, specifically itraconazole, oral ketoconazole, fluconazole, poconazole 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, disopyramide dofetilide, sotalol, hydroquinidine, quinidine)
- 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, saquinavir or teleprevir (these are protease inhibitors).
- 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 or 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.

Motilium 10 mg Tablets with food and drink

Take Motilium 10 mg Tablets before meals, as when taken after meals, the absorption of the medicine is slightly delayed.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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. Domperidone may cause unwanted side effects affecting the heart in a breast-fed baby. Domperidone 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

Do not drive or operate machines if you feel tired, sleepy or dizzy after taking your medicine.

Motilium 10 mg Tablets contain lactose (a type of sugar). If you have been told you have an intolerance to some sugars, consult your doctor before taking this medicine.

3. How to take Motilium 10 mg Tablets

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

Take Motilium 10 mg Tablets before meals, as when taken after meals, the absorption of the medicine is slightly delayed.

Duration of treatment

Symptoms usually resolve within 3-4 days of taking this medicine. Do not take Motilium 10 mg Tablets for longer than 7 days without consulting your doctor.

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

If you take more Motilium 10 mg Tablets than you should

If you have used or taken too much Motilium 10 mg Tablets, contact your doctor, pharmacist or the poison centre immediately, in particular if a child has taken too much. 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 10 mg Tablets

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.

Stop using this medicine and contact your doctor immediately if you experience any of the following unwanted events.

- Seizures
- Involuntary movements of the face or arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm
- A severe hypersensitivity reaction that may occur soon after administration that is characterised by skin rash, hives, itching, flushing, fainting, a swollen face and difficulty breathing among other possible symptoms (anaphylactic reaction)

Stop using this medicine and talk to your doctor if you experience any of the following unwanted events.

Common (may affect up to 1 in 10 people):

- Dry mouth

Uncommon (may affect up to 1 in 100 people):

- 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

Not known (frequency cannot be estimated from the available data)

- Hives
- Agitation or nervousness
- Feeling dizzy
- Restless legs syndrome (uncomfortable feeling, with an irresistible urge to move parts of your legs, and sometimes arms and other parts of your body)
- Eye movement disorder
- Inability to urinate
- Swollen breasts (even in men)

- Stop in menstrual periods
- Changes in certain laboratory test results. If you have a blood test to check your liver function tell your doctor or nurse if you are taking Motilium 10 mg Tablets.

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.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie;

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

5. How to store Motilium 10 mg Tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 30 °C. Do not refrigerate or freeze. Store in original package to protect from light.
- Do not use this medicine after the expiry date which is stated on the carton and blister after EXP or ΛΕΞΗ. The expiry date refers to the last day of that month.
- 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 10 mg Tablets contain

The active substance is domperidone. Each tablet contains 10 mg domperidone.

The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, pregelatinised potato starch, povidone, magnesium stearate, hydrogenated vegetable oil, sodium laurilsulfate, hypromellose

What Motilium 10 mg Tablets looks like and contents of the pack

Motilium 10 mg Tablets are off -white, film coated tablets available in packs of 10 tablets.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer

The manufacturer is Famar A.V.E., Anthoussa, Greece or Janssen-Cilag SA, 27100 val de Reuil, France or Lusomedicamenta Sociedade Técnica Farmacêutica SA, Estrada Consiglieri Pedroso, 69 – B, Queluz de Baixo, 2730-055 Barcarena, Portugal or Johnson & Johnson Consumer NV/SA, Antwerpeweg 15-17, 2340 Beerse, Belgium

PPA Number: 465/272/2

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