

**Package leaflet: Information for the user**  
**MOTILIUM® 30 mg Suppositories**  
(30mg domperidone per suppository)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start using 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 use MOTILIUM
3. How to use 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**

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 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)
- 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”).

This medicine is not suitable for neonates, infants and children less than 12 years of age and adolescents weighing less than 35 kg. If MOTILIUM is for a child, ask your doctor which formulation is appropriate.

**Warnings and precautions**

Before using 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 use a lower dose or use 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 in adults and children.

While using MOTILIUM, contact your doctor if you experience heart rhythm disorders such as palpitations, trouble breathing, loss of consciousness. Treatment with MOTILIUM should be stopped.

### **Taking other medicines**

Do not use 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, 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 telaprevir (these are protease inhibitors)
- cancer (e.g., toremifene, vandetanib, vincamine)

Do not use 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. 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.

### **Using 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 use 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 using this medicine.

### **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.

**Duration of treatment**

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

**Adults and adolescents (12 years of age and older and weighing 35 kg or more)**

The usual dose is one suppository two times a day. Do not use more than two suppositories per day.

**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.

**Neonates, infants, children less than 12 years of age and adolescents weighing less than 35 kg**

Suppositories are not suitable for neonates, infants or children less than 12 years of age or adolescents weighing less than 35 kg. If MOTILIUM is for a child, ask your doctor for the children's formulation.

**If you use more MOTILIUM than you should**

If you have used too much MOTILIUM, contact your doctor, pharmacist or the poison centre immediately, in particular if a child has used 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, gastric lavage, administration of activated charcoal and general supportive measures are recommended. Anticholinergic anti-Parkinson medication may help to counteract the extrapyramidal disorders.

**If you forget to use MOTILIUM**

Use 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 use 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 in adults and children.

**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

**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

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). 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 sight and reach 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. 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. Each suppository contains 30mg domperidone.

The other ingredients are: Tartaric acid, macrogol 4000, macrogol 1000, macrogol 400, butyl hydroxyanisol.

### **What MOTILIUM looks like and contents of the pack**

Each pack contains 6 white to slightly yellow suppositories in a cardboard carton.

### **Marketing authorisation holder and manufacturer**

#### **Marketing authorisation holder**

McNeil Healthcare (Ireland) Ltd.  
Airton Road  
Tallaght  
Dublin 24  
Ireland

#### **Manufacturer**

Janssen Pharmaceutica N.V.  
Turnhoutseweg 30  
B-2340  
Beerse  
Belgium

OR (for the 30mg only)

Lusomedicamenta Sociedade Técnica Farmacêutica, S.A.  
Estrada Consiglieri Pedroso 69-B  
Queluz de Baixo 2730-055 Barcarena,  
Portugal

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