
Patient Information Leaflet (PIL)

SCHEDULING STATUS

Schedule 4

MOTILIUM® tablets

10 mg domperidone per film-coated tablet.

Contains sugar (lactose monohydrate).

Each tablet contains 54,20 mg lactose monohydrate.

Read all of this leaflet carefully before you start using MOTILIUM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MOTILIUM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 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

MOTILIUM is used in adults and adolescents over 12 years of age and weighing over 35 kg for:

- Short term relief not exceeding 7 days for **stomach discomfort** due to food moving slowly through the stomach and intestines, where you may feel symptoms such as:
 - fullness during or shortly after a meal
 - a “heavy stomach”
 - bloated feeling
 - excessive belching
 - passing wind (flatulence)
 - nausea
 - vomiting
 - a burning feeling and/or pain in the stomach area
- Short term use not exceeding 7 days for **discomfort due to backflow of stomach acid**, where you may experience belching and/or heartburn
- Short term use not exceeding 7 days except when used for **nausea and vomiting** due to various causes including chemotherapy, radiotherapy or other medicines where use should not exceed 4 weeks.

2. What you need to know before you take MOTILIUM

MOTILIUM tablets are unsuitable for use in children at or less than 12 year of age

MOTILIUM tablets are unsuitable for use in adolescents weighing less or 35 kg body weight.

Do not use MOTILIUM

- if you are hypersensitive (allergic) to domperidone or any of the other ingredients in MOTILIUM (listed in section 6).
- if you suffer from a disease of the pituitary gland called prolactinoma.

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- if you have severe stomach cramps or persistent black stools.
 - if you have a liver disease.
 - if you are taking certain medicines that slow down the breakdown (metabolism) of other medicines in the body and can affect your heart rhythm, such as:
 - itraconazole, ketoconazole, posaconazole or voriconazole, which are used to treat fungal infections
 - erythromycin, clarithromycin or telithromycin or quinolones which are antibiotics
 - amiodarone, a heart medicine
 - ritonavir or saquinavir which are medicines for HIV/AIDS

If in doubt, ask your pharmacist or doctor for advice.

Stop taking MOTILIUM tablets and contact your doctor immediately if you experience an abnormal heart beat.

Warnings and precautions

Before taking MOTILIUM tablets, you should let your doctor know if you:

- have or had heart problems including heart failure, a previous heart attack, angina (chest pains), or heart rhythm disorders including a rapid or slow or irregular heart beat.
- have kidney problems
- if you are pregnant or breastfeeding your baby.

Stop taking MOTILIUM tablets and contact your doctor immediately if you experience an abnormal heart beat.

Other medicines and MOTILIUM:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Do NOT take MOTILIUM tablets if you are taking certain medicines that slow down the breaking down (metabolism) of other medicines in the body and can also affect your heart rhythm; such as:

- itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole, which are used to treat fungal infections
- erythromycin, clarithromycin or telithromycin or quinolones which are antibiotics
- amiodarone which is a heart medicine
- ritonavir or saquinavir which are medicines for HIV/AIDS.

If in doubt, ask your doctor or pharmacist for advice.

Tell your doctor or pharmacist if you are taking medicine to treat:

- fungal or bacterial infection
- heart problems
- malaria
- HIV/AIDS
- depression
- mental illness
- stomach problems
- cancer
- pain
- addictions

Your doctor will decide if these medicines can be taken together with MOTILIUM tablets or if you will need to be monitored closely for heart problem side effects.

Tell your doctor if you are taking anticholinergics (medicines to treat allergy, asthma, incontinence, gastrointestinal cramps, muscular spasms, depression or sleep disorders, for example, dextromethorphan or diphenhydramine) as these may affect MOTILIUM tablets.

Tell your doctor if you are taking medicine(s) for stomach acid. These medicines can be taken if you are also taking MOTILIUM tablets but they should not be taken at the same time. You should take oral MOTILIUM tablets before meals and the stomach acid medicine after meals.

Pregnancy and Breastfeeding:

You should not use MOTILIUM if you are pregnant.

You should not use MOTILIUM if breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using MOTILIUM.

Driving and using machines

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

MOTILIUM contains lactose monohydrate

The film coated tablets contain lactose and may not be suitable for people with:

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- lactose intolerance (inability to digest lactose, which is a sugar found in milk and milk products);
 - galactosemia or glucose-galactose malabsorption (inability to digest carbohydrates and sugars which are found in many foods including starches, milk and milk products).

3. How to use MOTILIUM

Do not share medicines prescribed for you with any other person.

Always take MOTILIUM tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with MOTILIUM tablets will last. Do not stop early because your symptoms may reappear. If you have the impression that the effect of MOTILIUM tablets is too strong or too weak, tell your doctor or pharmacist.

MOTILIUM tablets are most effective if taken a quarter to a half hour before the meal and, if needed, before you go to bed. Take MOTILIUM tablets with some liquid.

You should always take the lowest amount of MOTILIUM that works for you and you should not take it for longer than seven days. Although the amount of MOTILIUM you should usually take is described below, your doctor may adjust your dose to your personal needs.

When a doctor has prescribed MOTILIUM tablets for you, the following information applies: If MOTILIUM tablets are for nausea and vomiting, you should not usually need to take it for more than one week. Talk to your doctor if your nausea and vomiting lasts for more than one week.

If MOTILIUM tablets are for stomach discomfort, stomach acid backflow or nausea and vomiting due to chemotherapy, radiotherapy or other medicines, do not take MOTILIUM tablets for longer than 4 weeks without talking to your doctor.

ADULTS AND ADOLESCENTS OVER 35 kg

Take 1 of the 10 mg tablets three times per day with water. **Do not take more than 3 tablets per day.** The maximum dose per day is 30 mg.

USING MOTILIUM IN INFANTS AND CHILDREN

Do not give MOTILIUM to infants and children who are under 12 years of age and weigh less than 35 kg.

If you take more MOTILIUM tablets than you should:

If you have taken too much MOTILIUM tablets you may experience agitation, altered state of awareness or trance, seizure, sleepiness, confusion, uncontrolled movements, such as irregular eye movements, or abnormal posture, such as twisted neck. See your doctor, especially if a child has taken the medicine.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

4. Possible side effects

MOTILIUM can cause side effects.

Not all side effects reported for MOTILIUM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving MOTILIUM, please contact your health care provider for advice.

Listed below are side effects (also called adverse drug reactions) related to treatment with MOTILIUM tablets:

Stop treatment with MOTILIUM tablets and contact your doctor immediately if you experience any of the side-effects described below.

Frequently reported side effects

- Depression
- Anxiety
- Loss of interest in sex or diminished interest in sex
- Headache
- Sleepiness
- Restlessness
- Diarrhoea
- Rash
- Itchiness
- Enlarged or swollen breasts
- Painful or tender breasts
- Milk discharge from breasts or difficulty breast feeding
- Irregular or stopped menstrual periods
- A general feeling of weakness

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- Dry mouth
 - Feeling dizzy

Less frequently reported side effects:

- Movements that you cannot control, such as muscle tremors, spasms or stiffness, feeling restless or difficulty sitting still, slow movement
- Severe allergic reaction that may include:
 - a swollen face, lips, mouth, tongue or throat
 - difficulty swallowing or breathing
 - itchy rash (hives)
- Palpitations
- Seizures (fits)
- Unexpected death resulting from an abrupt loss of heart function in a person who may or may not have known heart disease.

Other less frequent side effects include:

- Hypersensitivity
- Hives
- Unusual discharge from breasts
- Feeling agitated
- Nervousness
- Inability to urinate
- Changes in certain laboratory test results.

Inadvertent ingestion in children resulted in:

- Movements that you cannot control, such as muscle tremors, spasms or stiffness, feeling restless or difficulty sitting still, slow movement.

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- Seizures.
 - Feeling agitated.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**” found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MOTILIUM.

5. How to store MOTILIUM

Store all medicine out of reach of children.

Store MOTILIUM film coated tablets at or below 30 °C (this is at a normal room temperature) and protect from light.

This medicine can be kept for only a limited period. Do not use MOTILIUM tablets after the date (month and year) printed after "EXP", even if it has been stored properly. You are advised to return old medicine to your pharmacist.

Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example!).

How to Dispose of MOTILIUM

- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MOTILIUM contains

The active ingredient in MOTILIUM tablets is domperidone. Each tablet contains 10 milligrams of domperidone.

The tablet also contains: lactose monohydrate, maize starch, microcrystalline cellulose, pregelatinised potato starch, polyvidone, magnesium stearate, hydrogenated cottonseed oil, sodium lauryl sulphate and hypromellose.

Contains sugar (lactose monohydrate).

What MOTILIUM looks like and contents of the pack

White circular, biconvex, film coated tablet 6,5 mm diameter engraved "M"

10 on one side and

"JANSSEN" on the other side.

MOTILIUM tablets are available in cartons containing one or more blister packs of 10.

Holder of Certificate of Registration



JANSSEN PHARMACEUTICA (PTY) LTD

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This leaflet was last revised in

- Date of registration of MOTILUM tablets: 18 May 1978
- Date of most recently revised Patient Information Leaflet as approved by Advisory Clinical Committee: 12 May 2022

Registration number

K/5.7.2/261

Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.