

MOTILIUM[®] Tablets

Domperidone base

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MOTILIUM tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MOTILIUM against the benefits this medicine is expected to have for you.

If you have any concerns about taking MOTILIUM ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What MOTILIUM is used for

MOTILIUM is used to treat the following conditions in adults:

- nausea and vomiting
- discomfort caused by a slow moving stomach known as gastroparesis. Symptoms include not being able to finish a meal, a feeling of being “too full” or bloated after a meal, a loss of appetite, feeling sick and maybe vomiting, or belching without relief.

MOTILIUM is an antiemetic and a prokinetic medicine. It works by blocking the action of a chemical messenger in the brain which causes the feeling of nausea and vomiting, as well as increasing the movement or contractions of the stomach and intestines, allowing food to move more easily through the stomach.

There is insufficient evidence to support use of MOTILIUM in childhood reflux disease.

MOTILIUM may not be suitable for chemotherapy or radiotherapy induced nausea and vomiting or vomiting after an operation.

MOTILIUM tablets are unsuitable for use in adults and adolescents weighing less than 35 kg.

MOTILIUM tablets are unsuitable for use in children <12 years of age and weighing less than 35 kg.

Your doctor may have prescribed MOTILIUM for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you take MOTILIUM

When you must not take it

Do not take MOTILIUM if:

- you have an allergy to MOTILIUM, or any of the ingredients. See **Product Description** at the end of this leaflet for a list of ingredients.
 - you have a tumour of the pituitary gland called prolactinoma.
 - an increase in stomach or bowel contractions can harm you. For example, if you have had bleeding, a blockage or puncture in your gastrointestinal tract
 - you are taking another medicine containing the active ingredient, itraconazole, posaconazole or voriconazole which is used to treat fungal infections
 - you are taking an antibiotic containing the active ingredient clarithromycin or telithromycin
 - You have moderate or severe liver failure.
 - You are taking another medicine containing the active ingredient ritonavir, saquinavir or telaprevir.
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MOTILIUM must not be given to children under 2 years of age

Do not use MOTILIUM if the original packaging is torn or shows signs of tampering. Do not use MOTILIUM beyond the expiry date (month and year) printed on the pack.

Before you start to take it

You must tell your doctor if:

- you have current or history of heart disease and/or high blood pressure, high cholesterol, obesity, smoking and excessive alcohol consumption.
- you are pregnant or planning to become pregnant
- you are breast feeding or wish to breastfeed
- you have or have ever had liver or kidney disease
- you have or have ever had breast cancer
- you are not able to digest lactose which is a sugar found in milk and milk products.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given MOTILIUM.

Your doctor will advise you whether or not to take MOTILIUM or if you need to adjust the dose or alter your treatment.

Taking other medicines:

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- medicines for treating fungal infections, such as, itraconazole, voriconazole and pentamidine
- medicines that neutralise or reduce the amount of stomach acid (such as antacids, ranitidine, cimetidine, omeprazole). Take these medicines after meals, and not before meals
- anticholinergic drugs (used to prevent travel sickness, treat Parkinson's Disease or relieve stomach cramps or spasms)
- an antibiotic, such as erythromycin, levofloxacin and moxifloxacin
- medicines used to treat HIV infections, such as amprenavir, atazanavir, fosamprenavir, indinavir and nelfinavir
- medicines used to treat high blood pressure or chest pain, such as verapamil and diltiazem
- medicines used to treat hallucinations and delusions such as haloperidol, pimozide, sertindole
- medicines used to treat malaria such as halofantrine
- amiodarone, dofetilide, dronedarone, ibutilide and sotalol used to treat fast heart rate
- disopyramide and quinidine used to treat irregular heart rate
- aprepitant used to treat nausea and vomiting
- dolasetron used to treat gastro intestinal issues
- an antidepressant called nefazodone, citalopram and escitalopram
- certain drugs used in cancer such as toremifene and vandetanib
- certain other drugs (e.g., bepridil and methadone)
- Antacids or drugs that inhibit or diminish secretion should not be used simultaneously with MOTILIUM as they may affect the absorption of MOTILIUM. When used concomitantly, MOTILIUM should be taken before meals and antacids or drugs that inhibit secretion

These medicines may be affected by MOTILIUM or may affect how well MOTILIUM works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Taking MOTILIUM

How much to take:

- Adults and adolescents ≥ 12 years of age and weighing ≥ 35 kg, and children < 12 years of age and weighing ≥ 35 kg: The usual dose is 1 tablet three to four times a day, best taken 15 to 30 minutes before meals or food, and if necessary at bedtime.
- You should not take more than a total of four tablets in a single day.
- Your doctor may reduce the dose if you have kidney disease.
- Your doctor may ask you to take MOTILIUM for a maximum of one week for the treatment of acute nausea and vomiting.
- MOTILIUM tablets are unsuitable for use in adults and adolescents weighing less than 35 kg.
- In children who are under 12 years of age, MOTILIUM can only be used if the child weighs 35 kg or more. Do not give MOTILIUM to infants and children who are under 12 years of age and weigh less than 35 kg.
- MOTILIUM must not be given to children under 2 years of age.

How to take it:

- MOTILIUM is best taken 15 to 30 minutes before meals or food.
- Do not take medicines that neutralise stomach acid or medicines that reduce the production of stomach acid within 2 hours of taking MOTILIUM. This is because sufficient stomach acid is required to ensure that MOTILIUM is properly absorbed by the body.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If you forget to take it

- Take your dose as soon as you remember, and then continue to take it as you would normally.
- If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
- Do not take a double dose to make up for the dose you missed.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you have taken too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Poisons Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 POISON (or 0800 764 766)

Keep these telephone numbers handy.

If you take too much MOTILIUM you may experience drowsiness, agitation, convulsion, altered consciousness, confusion and uncontrolled movements.

While you are taking MOTILIUM

Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant while taking MOTILIUM.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking MOTILIUM.

Things you must not do

- Do not use MOTILIUM to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Dizziness and sleepiness/drowsiness have been observed following use of MOTILIUM therefore do not drive or use machinery or engage in other activities requiring mental alertness and coordination until you know how MOTILIUM affects you.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following:

- headache, trouble sleeping, nervousness, dizziness, tiredness or irritability
- sleepiness or drowsiness, fits or seizures, agitation
- dry mouth or thirst
- stomach cramps, diarrhoea, constipation, nausea, changes in appetite or heartburn
- rash or itchy skin
- itchy eyes and crusty eyelids with discharge
- mouth ulcers or cold sores.

These are mild side effects of MOTILIUM. Tell your doctor if they continue.

- uncontrollable movements
- irregular or no menstrual period
- unusual secretion of breast milk or decrease in sex drive in men or women
- breast tenderness or breast enlargement in men and women.

These effects will reverse on stopping treatment.

Tell your doctor immediately if you notice any of the following as you may need urgent medical care:

- fast or irregular heart beats
- swelling of hands, ankles or feet
- difficulty passing urine or pain when passing urine.

STOP using MOTILIUM and tell your doctor immediately if any of the following happen:

- you have an allergic reaction to MOTILIUM (allergy can be recognised, for instance, by skin rash, itching, shortness of breath and/or swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing)

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After taking MOTILIUM

Storage

Keep MOTILIUM tablets in the pack until it is time to take them.

Keep MOTILIUM tablets in a cool dry place where the temperature is below 30°C

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Do not store MOTILIUM tablets, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on windowsills. Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking MOTILIUM tablets, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine which may be left over.

Product Description

What it looks like

MOTILIUM tablets are white, circular, film-coated, biconvex tablets with “M/10” imprinted on one side and “JANSSEN” on the other.

They are available in blister in carton of 100 tablets.

Ingredients

Each MOTILIUM tablet contains:

- 10 mg of domperidone as the active ingredient.
- lactose, maize starch, microcrystalline cellulose, pregelatinized potato starch, povidone, magnesium stearate, hydrogenated cottonseed oil, sodium lauryl sulfate and hypromellose.

Sponsor

Janssen-Cilag Pty Ltd

NZ Office: Auckland, NEW ZEALAND

Telephone: (09) 588 1398 or 0800 800 806

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