

MOTILIUM® Tablets

Domperidone

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed MOTILIUM for another reason.

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.
- you have or have had liver disease
- an increase in stomach or bowel contractions, for example, if you have had bleeding, a blockage or puncture in your gastrointestinal tract
- you have problems with your heart, including abnormal heart beat
- you are taking another medicine containing the active ingredient ketoconazole, voriconazole, itraconazole, posaconazole which is used to treat fungal infections.
- you are taking another medicine containing the active ingredient ritonavir or saquinavir which is used to treat HIV.

- you are taking another medicine containing the active ingredient telaprevir which is used to treat hepatitis C.
- you are taking an antibiotic containing the active ingredient erythromycin, clarithromycin or telithromycin.

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 are pregnant or planning to become pregnant
- you are breast feeding or wish to breastfeed
- you have a pre-existing heart condition
- you have or have ever had 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.

MOTILIUM should not be used in children.

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 any that you get without a prescription from your pharmacy, supermarket or health food shop.

Do not take MOTILIUM if you are taking 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, posaconazole, or voriconazole, which are used to treat fungal infections
- erythromycin, clarithromycin, or telithromycin which are antibiotics
- amiodarone which is a heart medicine
- ritonavir or saquinavir which are medicines for HIV/AIDS
- teleprevir which is a medicine for hepatitis C

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

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

- medicines for treating fungal infections, such as ketoconazole, fluconazole, itraconazole and voriconazole
- anticholinergic drugs (medicines to treat allergy, asthma, incontinence, gastrointestinal cramps, muscular spasms, depression or sleep disorders, for example, dextromethorphan or diphenhydramine)
- dopaminergic agonists (used to treat Parkinson's Disease or digestive disorders)
- an antibiotic, such as clarithromycin, telithromycin and erythromycin
- medicines used to treat HIV infections, such as amprenavir, atazanavir, fosamprenavir, indinavir, nelfinavir, ritonavir and saquinavir
- medicines used to treat high blood pressure or chest pain, such as diltiazem and verapamil

- amiodarone used to treat fast heart rate
- aprepitant used to treat nausea and vomiting
- an antidepressant called nefazodone
- medicines that neutralise or reduce the amount of stomach acid, such as antacids. 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.

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.

How to take MOTILIUM

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take

Adults:

- The usual dose in adults is one tablet three times a day.
- For nausea and vomiting this medicine is usually used for a maximum of 1 week.

The other conditions the initial duration of treatment is up to a maximum of 4 weeks.

How to take it

MOTILIUM is best taken 15 to 30 minutes before meals, and if necessary at bedtime.

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

If you forget to take it

- Try to take each dose at the scheduled time.
- The missed dose should be omitted and the actual dosing schedule resumed. 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 to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much MOTILIUM. 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 764766)

Keep these telephone numbers handy.

If you take too much MOTILIUM you may experience agitation,

seizure, drowsiness, confusion and uncontrolled movements, such as irregular eye movements, or abnormal posture like twisted neck.

While you are using MOTILIUM

A risk of unusual heart beat or sudden heart failure has been associated with MOTILIUM use. The risk is higher in patients older than 60 years or taking more than three tablets daily. MOTILIUM should be used with caution and should be taken at the lowest effective dose, particularly in older patients. Talk to your doctor if you have a pre-existing heart condition. Treatment with MOTILIUM should be stopped if signs or symptoms occur that may be associated with unusual heart beat, please talk to your doctor for advice.

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 drive or use machinery or engage in other activities requiring mental alertness or co-ordination until you know how this medication affects you.
- 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.

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, depression, dizziness, tiredness or irritability
- sleepiness or drowsiness, fits or seizures, agitation
- dry mouth or thirst
- regurgitation, 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 of the face or arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm
- 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
- passing urine more frequent 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 using 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 or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

MOTILIUM tablets are white, film coated, round tablets. Each tablet is

marked "M/10" on one side and "JANSSEN" on the reverse. They are available in blister in carton of 25 or 100 tablets. (AUST R 39510)

Ingredients

Each MOTILIUM tablet contains:

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

Sponsor

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