

MOTILIUM[®] TABLET

Domperidone (10mg,)

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What MOTILIUM[®] is used for

MOTILIUM[®] is used for:

- the relief of the symptoms of nausea and vomiting from various causes (including chemotherapy, radiotherapy or other medicines).

How MOTILIUM[®] works

MOTILIUM[®] 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.

Before you use MOTILIUM[®]

- When you must not use it

- You should not use MOTILIUM[®] if:
- you know you are allergic (hypersensitive) to domperidone and other ingredients listed at the end of the leaflet
 - you suffer from a tumor of the pituitary gland called prolactinoma
 - have bleeding, obstruction and hole in the stomach and bowel (e.g. severe stomach cramps or persistent black stools)
 - have moderate to severe liver disease
 - have abnormal potassium level, low magnesium level in the blood
 - have or had heart problems including heart failure or heart rhythm disorders including a slow or irregular heartbeat

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

Stop taking MOTILIUM[®] and contact your doctor immediately if you experience abnormal heart beat.

Pregnancy and lactation

If you are pregnant or think you may be, tell your doctor, who will decide if you can take MOTILIUM[®].

Breast-feeding

Small amounts of MOTILIUM[®] can end up in the mother's milk. Breast-feeding is not recommended for mothers who are taking MOTILIUM[®]. Talk to your doctor if you have any questions.

- Before you start use it

Before taking MOTILIUM[®], you should let your doctor know if you have severe kidney problems.

If you are older than 60 years of age, talk to your doctor before taking this medicine. MOTILIUM[®] should be used with caution in older patients.

The *film-coated tablets* contain lactose and may not be suitable if you have:

- 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).

If you have any of these conditions, talk to your doctor before taking MOTILIUM[®].

- Taking other medicines

Always tell your doctor or pharmacist if you are taking any medicines, including those available without a prescription.

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

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

- heart problems (disopyramide, quinidine, amiodarone, dofetilide, dronedarone, ibutilide, sotalol)
- mental illnesses (haloperidol, pimozide, sertindole)
- depression (citalopram, escitalopram)

- bacterial infections (levofloxacin, moxifloxacin)
- fungal infection (pentamidine)
- malaria (halofantrine)
- stomach problems (dolasetron)
- cancer (toremifene, vandetanib)
- other illnesses (bepidil, methadone)

Your doctor will decide if these medicines can be taken together with MOTILIUM[®] 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 or cough, for example, dextromethorphan or diphenhydramine) as these may affect MOTILIUM[®].

Tell your doctor if you are taking medicine(s) for stomach acid. These medicines can be taken if you are also taking MOTILIUM[®] 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.

How to use MOTILIUM[®]

- How much to use

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

MOTILIUM[®] is most effective if taken 15-30 minutes before meals.

Adults and adolescents (12 years of age and over) weighing 35 kg or more; children weighing 35kg or more:

Film coated tablets:

- Take 1 tablet 3 to 4 times a day.
- Do not take more than 4 tablets per day (40 mg/day).

- When to use it

MOTILIUM[®] is most effective if taken 15-30 minutes before meals and, if needed, before you go to bed.

- <u>How long to use it</u> When MOTILIUM® has not been prescribed for you by a doctor, the following information applies: If MOTILIUM® is used for short term 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. For other indications, the initial duration of treatment is up to four weeks. - <u>If you forget to use it</u> 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. - <u>If you use too much (overdose)</u> Overdose has been reported primarily in infants and children. If you have taken too much MOTILIUM® you may experience agitation, altered state of awareness, seizure, confusion, sleepiness, uncontrolled movements. See your doctor, especially if a child has taken the medicine.	Do not take any new medicines without consulting your doctor. Do not give MOTILIUM® to anyone else, even if they have the same symptoms or condition as you. - <u>Things to be careful of</u> <u>Driving and using machines</u> Do not drive or operate machines if you feel tired, sleepy or dizzy after taking your medicine. Side effects You may experience unwanted effects when using MOTILIUM®. Listed below are side effects (also called adverse reactions) related to treatment with MOTILIUM®: <i>Very rare</i> (reported by fewer than 1 in 10000 people): • Severe allergic reaction that may include: ○ A swollen face, lips, mouth, tongue or throat ○ Difficulty swallowing or breathing ○ Itchy rashes (hives) • Abnormal heart rhythm • Unexpected death resulting from an abrupt loss of heart function in a person who may or may not have known heart disease. Stop taking 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.	• Irregular menstrual periods in women • A general feeling of weakness <i>Uncommon</i> (reported by at least 1 in 1000 people but fewer than 1 in 100 people): • Hypersensitivity • Hives • Unusual discharge from breasts • Swollen breasts If your child experience any of these effects, stop taking MOTILIUM® and consult your doctor immediately. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]. Storage and disposal of MOTILIUM® - <u>Storage</u> Store below 30°C. Keep out of the reach of children. This medicine can be kept for only a limited period. Do not use MOTILIUM® 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. - <u>Disposal</u> 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.
While you are using it - <u>Things you must do</u> Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking MOTILIUM®. Tell your doctor immediately if you become pregnant while taking this medication. - <u>Things you must not do</u> Do not stop taking the medicine unless advised by your doctor.	<i>Common</i> (reported by at least 1 in 100 people but fewer than 1 in 10 people): • Depression • Anxiety • Loss or diminished interest in sex • Headache • Sleepiness • Restlessness • Diarrhea • Rash • Itchiness • Painful or tender breasts • Milk discharge from breasts or difficulty breast feeding	Product description - <u>What it looks like</u> <i>Film coated tablets:</i> • Blister packs with 10mg tablets • White to faintly cream-colored round biconvex, film-coated tablet with the inscription "JANSSEN" on one side and "M" on the other side - <u>Ingredients</u> - Active ingredient Domperidone - Inactive ingredients <i>Film coated tablets:</i>

Lactose, maize starch,
microcrystalline cellulose,
pregelatinized potato starch,
polyvidone, magnesium stearate,
hydrogenated vegetable oil, sodium
lauryl sulphate, hypromellose.

- MAL numbers:

Film coated tablets:

MAL19872254ARZ

Manufacturer

Film coated tablets:

JNTL Consumer Health (France)

S.A.S.Domaine De Maigremont, 27100

Val De Reuil, France

Product registration holder

JNTL(Malaysia) Sdn.Bhd.

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46050 Petaling Jaya

Selangor, Malaysia

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