

MOTILIUM[®] ORAL SUSPENSION

Domperidone (10mg, 1mg/ml)

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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[®] oral suspension contains sorbitol and may not be suitable if you have sorbitol intolerance/hereditary fructose intolerance (inability to tolerate fructose, which can run in families; fructose is a sugar found in fruit and fruit juices).

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 (bepridil, methadone)

Do not take MOTILIUM[®] if you are taking clarithromycin (antibiotic).

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[®] oral suspension 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:

Oral suspension:

- Take 1 full dosing cupfuls (10mL) of oral suspension 3 or 4 times a day.
- Do not take more than 40mL per day (40 mg/day).

Adults and adolescents weighing less than 35 kg:

Oral suspension:

- Give 0.25 milliliters of the oral suspension per kilogram of body weight 3 or 4 times a day. The maximum dose per day is 1 mg/kg but do not exceed 35 mg per day.

<p><i>Infants and children less than 12 years of age and weighing less than 35kg:</i> The effectiveness of MOTILIUM® has not been established in infants and children under 12 years of age with a body weight of <35 kg.</p> <p>- <u>When to use it</u> MOTILIUM® is most effective if taken 15-30 minutes before meals and, if needed, before you go to bed.</p> <p>- <u>How long to use it</u> When MOTILIUM® has not been prescribed for you by a doctor, the following information applies:</p> <p>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.</p> <p>For other indications, the initial duration of treatment is up to four weeks.</p> <p>- <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.</p> <p>If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.</p> <p>Do not take a double dose to make up for the dose you missed.</p> <p>If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.</p> <p>- <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.</p> <p>While you are using it</p> <p>- <u>Things you must do</u> Take your medicine exactly as your doctor has told you.</p>	<p>Tell all the doctors, dentists and pharmacists treating you that you are taking MOTILIUM®.</p> <p>Tell your doctor immediately if you become pregnant while taking this medication.</p> <p>- <u>Things you must not do</u> Do not stop taking the medicine unless advised by your doctor.</p> <p>Do not take any new medicines without consulting your doctor.</p> <p>Do not give MOTILIUM® to anyone else, even if they have the same symptoms or condition as you.</p> <p>- <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.</p> <p>Side effects You may experience unwanted effects when using MOTILIUM®. Listed below are side effects (also called adverse reactions) related to treatment with MOTILIUM®:</p> <p><i>Very rare</i> (reported by fewer than 1 in 10000 people):</p> <ul style="list-style-type: none"> • Severe allergic reaction that may include: <ul style="list-style-type: none"> ○ 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. <p>Stop taking MOTILIUM® and contact your doctor immediately if you experience any of the unwanted events described above.</p> <p>Other unwanted effects that have been observed with MOTILIUM® are listed below.</p> <p><i>Common</i> (reported by at least 1 in 100 people but fewer than 1 in 10 people):</p> <ul style="list-style-type: none"> • Depression 	<ul style="list-style-type: none"> • 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 • Irregular menstrual periods in women • A general feeling of weakness <p><i>Uncommon</i> (reported by at least 1 in 1000 people but fewer than 1 in 100 people):</p> <ul style="list-style-type: none"> • Hypersensitivity • Hives • Unusual discharge from breasts • Swollen breasts <p>If your child experience any of these effects, stop taking MOTILIUM® and consult your doctor immediately.</p> <p>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)].</p> <p>Storage and disposal of MOTILIUM®</p> <p>- <u>Storage</u> Store below 30°C. Keep out of the reach of children.</p> <p>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.</p> <p>- <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.</p> <p>Product description</p> <p>- <u>What it looks like</u> <i>Oral suspension:</i></p>
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- 100ml and 200ml glass bottles with a measuring cap of 10 ml or a sucking pipette 5 ml.
- White oral suspension

Ingredients

- Active ingredient
Domperidone

- Inactive ingredients

Oral suspension:

Sodium saccharin, microcrystalline cellulose and sodium carboxymethylcellulose, sorbitol liquid non-crystallising, methylparahydroxybenzoate, propylparahydroxy-benzoate, sodium hydroxide, polysorbate, purified water.

- **MAL numbers:**

Oral suspension:

MAL19872253ARZ

Instructions of use and handling

Oral suspension:

Mix the contents of the bottle completely using a gentle titling motion to avoid the formation of foam.

Directions for opening the bottle:

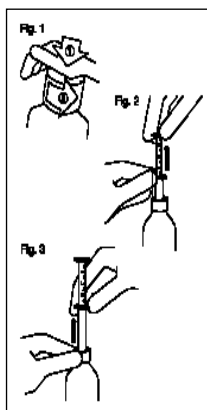


Fig. 1: The bottle comes with a childproof cap, and should be opened as follows:

- Push the plastic screw cap down while turning it counter-clockwise.
- Remove the unscrewed cap.

Directions for using the pipette (supplied with the 100mL bottle only)

Fig. 2: Insert the pipette into the bottle. While holding the bottom ring, pull the top ring up to the mark corresponding to the child's weight in kilograms.

Fig. 3: Holding the bottom ring, remove the entire pipette from the bottle.

Empty the pipette.
Close the bottle.

Rinse the pipette with some water.

Directions for using the measuring cup



A measuring cup is supplied with the MOTILIUM® oral suspension. Pour the oral suspension into the measuring cup. When you take the measuring cup off and the arrow is pointing upwards, that is already the correct side to fill..

Manufacturer

Oral suspension:

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

Product registration holder

Johnson & Johnson Sdn Bhd (3718-D)
Level 8, The Pinnacle,
Persiaran Lagoon, Bandar Sunway,
46150, Petaling Jaya, Selangor, Malaysia

Date of revision

18/04/2023 (MY PI CCDS vJan2018 + HA directives)

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