

Motilium 10mg Suppositories

Motilium 30mg Suppositories

Motilium 60mg Suppositories

domperidone

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Motilium is and what it is used for
2. Before you use Motilium
3. How to use Motilium
4. Possible side effects
5. How to store Motilium
6. Further information

1. WHAT MOTILIUM IS AND WHAT IT IS USED FOR

Motilium is a medicine that increases the movements or contractions of the stomach or bowel.

Motilium 10 and 30 mg suppositories are used in children to treat nausea (feeling sick) and vomiting (being sick).

Motilium 60 mg suppositories are used in adults to treat the following symptoms: nausea (feeling sick) and vomiting (being sick), a heavy stomach or bloating, a sensation of discomfort in the stomach area or when stomach contents flow back into the gullet, as with belching and heartburn.

2. BEFORE YOU USE MOTILIUM

Do not use Motilium if you are:

- Allergic (hypersensitive) to domperidone or any of the other ingredients of Motilium.
- Have stomach bleeding or if you regularly have severe abdominal pain or persistent black stools (poo).
- Have a blocked or perforated gut
- Have a tumour of the pituitary gland (prolactinoma).
- Taking certain medicines that slow down the metabolism (the breaking down) of other medicines in the body and can also affect your heart rhythm such as ketoconazole, fluconazole, or voriconazole, which are used to treat fungal infections, the antibiotics erythromycin, clarithromycin or telithromycin; or amiodarone, a heart medicine.
- If you have or have had liver disease.

Take special care with Motilium:

- If you have kidney problems, follow your doctor's instructions carefully.
- If you are also taking other medicines. Please also read "Using other medicines" section.

The 10mg and 30mg suppositories are not suitable for children weighing less than 5 kg

The 60 mg suppositories are only suitable for adults and adolescents over 12 years of age and weighing more than 35 kg.

Use in young children

When Motilium is used in young children, there is a small chance they might develop abnormal muscle movements or tremor (shaking). It is important to strictly keep to the dosage as prescribed by your doctor or as instructed in this leaflet.

Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or in those taking doses higher than 30 mg per day. Domperidone should be used at the lowest effective dose in adults and children.

Duration of use

Do not take Motilium for longer than 14 days unless prescribed by your doctor.

Using other medicines

Do not take MOTILIUM if you are taking oral ketoconazole (a medicine for fungal infections), or oral erythromycin (an antibiotic) or certain medicines that slow the metabolism (the breaking down) of other medicines in the body and can also affect your heart rhythm.

Tell your doctor or pharmacist if you are taking drugs to treat infection, heart problems or AIDS/HIV, the antidepressant nefazadone, or aprepitant, a medicine used to reduce nausea associated with cancer chemotherapy.

It is important to ask your doctor or pharmacist if Motilium is safe for you when you are taking any other medicines, including medicines obtained without prescription.

Taking MOTILIUM with food and drink

The absorption of Motilium Suppositories is not affected by food or drink.

Pregnancy It is not known whether the use of Motilium is harmful during pregnancy. If you are pregnant or think you may be inform your doctor who will decide if you can take Motilium.

Breast feeding Small amounts of Motilium have been detected in breast milk. Therefore the use of Motilium is not recommended for nursing mothers.

Always ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines Motilium does not affect your ability to drive or use machines.

Important information about some of the ingredients of Motilium:

Motilium suppositories contain an ingredient called butylated hydroxyanisole which can irritate eyes, skin and the lining of the mouth and nose (mucous membranes). If you think you have such a reaction please tell your doctor.

3. HOW TO USE MOTILIUM SUPPOSITORIES

Follow these instructions closely unless your doctor has advised you otherwise.

If you are unsure of anything, consult your doctor or pharmacist. If you do not feel better after 2 weeks, make sure you consult your doctor.

Adults and adolescents over 12 years of age and with a body weight of 35 kg or more)

The normal dose is one 60 mg suppository twice daily.

Children 12 years of age or less with a body weight of 5 kg or more

- Your doctor will explain to you exactly how much of this medicine to give to the child, and how often, because the dose is dependent on the weight of the child.

- The normal dose for a child weighing 5 to 15kg is one 10mg suppository twice daily.
- The normal dose for a child weighing more than 15kg is one 30mg suppository twice daily.
- MOTILIUM suppositories are not suitable for children weighing less than 5 kg.

Inserting the suppositories

- First wash your hands.
- The suppository should be moistened and then inserted into the bottom as far as possible.
- Once this has been done tense your muscles to prevent the suppository coming out.

If you take more Motilium than you should: In the event of an overdose, agitation, altered state of awareness or trance, seizure, confusion, sleepiness, uncontrolled movements, such as irregular eye movements, or abnormal posture, such as twisted neck can occur. When you have used or taken too much Motilium, contact your doctor, pharmacist or the poison centre immediately in particular when a child has taken too much, and also if you/they have swallowed the suppository. Information for the doctor: Close observation of the patient, gastric lavage, administration of activated charcoal and general supportive measures are recommended. Anticholinergic anti-Parkinson medication may help to counteract the extrapyramidal reactions.

If you forget to take Motilium suppositories:

If you miss a dose, take the next dose as soon as possible. However, if it is almost time to take the next dose, forget about the missed dose and continue as normal. Do not take a double dose to make up for forgotten missed dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Motilium can have side effects although not everybody gets them.

Very rare (reported by fewer than 1 in 10,000 patients):

- Seizures
- Involuntary movements of the face or arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm
- A type of reaction that may occur soon after administration and is recognized by skin rash, itching, shortness of breath, and/or a swollen face
- A severe hypersensitivity reaction that may occur soon after administration that is characterized by hives, itching, flushing, fainting, and difficulty breathing among other possible symptoms
- Heart rhythm disorder
- Unexpected death resulting from an abrupt loss of heart function in a person who may or may not have known heart disease

Stop treatment with domperidone 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:

Common (reported by at least 1 in 100 patients but fewer than 1 in 10 patients):

- Dry mouth

Uncommon (reported by at least 1 in 1000 patients but fewer than 1 in 100 patients):

- Anxiety
- Loss of interest in sex or diminished interest in sex
- Headache
- Sleepiness
- Diarrhoea
- Rash
- Itchiness
- Painful or tender breasts
- Milk discharge from breasts
- A general feeling of weakness

Rare (reported by at least 1 in 10,000 patients but fewer than 1 in 1000 patients):

- Stopped menstrual periods in women

Very Rare (reported by fewer than 1 in 10,000 patients):

- Hives
- Agitation
- Nervousness
- Inability to urinate

- Changes in certain laboratory test results. Some patients who have used Motilium for conditions and dosages requiring medical oversight have experienced the following unwanted effects: Restlessness; swollen or enlarged breasts, unusual discharge from breasts, irregular menstrual periods in women, difficulty breastfeeding, depression, hypersensitivity.

Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or in those taking doses higher than 30 mg per day. Domperidone should be used at the lowest effective dose in adults and children.

If any of these unwanted effects occur, consult your doctor or pharmacist immediately. If you experience a side effect that is not mentioned in this leaflet or that you feel is serious, notify your doctor or pharmacist.

5. HOW TO STORE MOTILIUM

Keep the medicine out of the reach and sight of children

- Do not use Motilium after the expiry date which is stated on the pack. The expiry date “exp.” Refers to the last day of the month shown where the first two figures indicate the month, the next the year.

Do not store above 25°C. Do not refrigerate or freeze.

Keep container in the outer carton to protect from light.

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.

6. FURTHER INFORMATION

What Motilium contains

The active substance is domperidone. Each suppository contains 10mg, 30mg or 60mg domperidone.

The other ingredients are:

Tartaric acid, macrogol 4000, macrogol 1000, macrogol 400, butylated hydroxyanisole.

What Motilium looks like and the contents of the pack

Each pack contains 6 white to slightly yellow suppositories in a cardboard carton.

Marketing authorisation holder

McNeil Healthcare (Ireland) Ltd.

Airton Road

Tallaght

Dublin 24

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Manufacturer:

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