

Motilium 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 taking doses higher than 30mg per day. Motilium should be used at the lowest effective dose in adults and children.

Side effects such as feeling drowsy, nervous, agitated or irritable or having a fit are more likely to happen in children.

Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE MOTILIUM

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not take Motilium Tablets after the expiry date stated on the pack.
- Ask your pharmacist how to dispose of medicines you no longer need. Do not dispose of medicines by flushing down a toilet or sink, or by throwing them out with your normal household rubbish. This will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Motilium 10mg Film-Coated Tablets contain

Each Motilium Tablet contains 10mg of domperidone (the active ingredient). It also contains lactose, maize starch, microcrystalline cellulose, hypromellose, pregelatinised starch, povidone, propylene glycol, magnesium stearate, silica colloidal hydrated and polysorbate 20.

What Motilium 10mg Film-Coated Tablets look like and contents of the pack

Each pack contains 30 or 100 white to cream coloured, film-coated tablets with Motilium stamped on one side.

Marketing Authorisation Holder is:

Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

Manufacturer is:

Fawdon Manufacturing Centre, Edgefield Avenue, Fawdon, Newcastle-upon-Tyne, Tyne & Wear, NE3 3TT.

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MOTILIUM
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MOTILIUM 10 MG FILM-COATED TABLETS

Domperidone

PATIENT INFORMATION LEAFLET

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect

In this leaflet:

1. What Motilium is and what it is used for
2. What you need to know before you take Motilium
3. How to take Motilium
4. Possible side effects
5. How to store Motilium
6. Contents of the pack and other information

1. WHAT MOTILIUM IS AND WHAT IT IS USED FOR

The name of your medicine is Motilium 10mg Film-Coated Tablets (called Motilium in this leaflet). Motilium contains a medicine called domperidone. This belongs to a group of medicines called 'dopamine antagonists'.

Motilium works by helping to move food faster through your food pipe (oesophagus), stomach and gut. This is so that it does not stay in the same place for too long. It also helps stop food flowing the wrong way back up your food pipe.

Motilium can be used for the following:

Adults

- To stop or prevent you feeling sick (nausea) or being sick (vomiting)
- To stop or prevent the feeling of fullness during or shortly after a meal
- To treat stomach discomfort, or heartburn caused by the flow of the stomach contents back into your food pipe

Children

- To stop or prevent children feeling sick (nausea) or being sick (vomiting)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MOTILIUM

Do not take Motilium tablets if:

- You are allergic (hypersensitive) to domperidone or any of the other ingredients of Motilium 10mg Film-Coated Tablets (listed in section 6: Contents of the pack and other information). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have a tumour of the pituitary gland (prolactinoma)
- You have a blockage or tear in your intestines
- You have black, tarry bowel motions (stools) or notice blood in your bowel motions. This could be a sign of bleeding in the stomach or intestines.
- If you have or have had liver problems.

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Do not take Motilium if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Motilium.

Take special care with Motilium and check with your doctor or pharmacist before taking this medicine if:

- You have any kidney problems. If you take Motilium over a long period, your doctor may want to lower the amount you use. This will depend on how severe your kidney problems are

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Motilium. Do this even if they have applied in the past.

Motilium 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 taking doses higher than 30mg per day. Motilium should be used at the lowest effective dose in adults and children.

Other medicines and Motilium

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you can buy without a prescription, including herbal medicines. This is because Motilium can affect the way some other medicines work. Also, some medicines can affect the way Motilium works.

Do not use Motilium and tell your doctor if you are taking any of the following:

- Ketoconazole tablets or liquid for fungal infections
- Antibiotics for infections (such as erythromycin)

Taking Motilium with food and drink

It is recommended to take Motilium before meals, as when taken after meals the absorption of the medicine is slightly delayed.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking Motilium if:

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding. It is best not to take Motilium if you are breast-feeding. This is because small amounts may pass into the mother's milk

Driving and using machines:

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

Important information about some of the ingredients of Motilium tablets

This medicine contains lactose. If you have been told that you cannot digest or tolerate some sugars, talk to your doctor before taking Motilium.

3. HOW TO TAKE MOTILIUM

Always take Motilium tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Swallow the tablets whole with a drink of water.
- Take the tablets 15 to 30 minutes before a meal and, if needed, before you go to bed.
- Do not crush or chew them.

The usual dose is:

- **Adults and teenagers** (over 12 years and who weigh more than 35 kg)
Take one or two Motilium tablets (10 or 20mg) 3 to 4 times a day.
Do not take more than 8 tablets (80 mg) in a day.
- **Use in children**
Do not give Motilium tablets to children under 12 years of age and weighing less than 35kg.

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People with kidney problems

Your doctor may tell you to take a lower dose or to take the medicine less often.

How long can I take this medicine for?

Your doctor will decide how long you will need to take this medicine.

If you take Motilium tablets for more than 2 weeks your doctor may wish to see you again. This is to check if you need to keep taking the treatment.

If you take more Motilium than you should:

- If you have taken more Motilium tablets than you should, talk to a doctor or go to the nearest hospital casualty department straight away. Take the carton and any tablets left with you. This is so the doctors know what you have taken.
- The signs of taking more than you should include feeling sleepy, confused, uncontrolled movements (especially in children) which include unusual eye movements, unusual movements of the tongue or abnormal posture (such as a twisted neck).

If you forget to take Motilium:

- If you forget to take Motilium, take it as soon as you remember.
- However if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

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

Stop taking Motilium and see your doctor or go to a hospital straightaway if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to Motilium.
- You notice any uncontrolled movements. These include irregular eye movements, unusual movements of the tongue, and abnormal posture such as a twisted neck, trembling and muscle stiffness. This is more likely to happen in children. These symptoms should stop once you stop taking Motilium.
- You have a very fast or unusual heartbeat. This could be a sign of a life-threatening heart problem.

Other side effects include:

Rare (affects less than 1 in 1,000 people)

- Unusual production of breast milk in men and women
- Breast enlargement in men
- Lowering of sexual drive (libido) in men
- In women, menstrual periods may be irregular or stop
- Stomach problems, including mild stomach cramps.

Very rare (affects less than 1 in 10,000 people)

- Itchy skin. You may also have a rash
- A blood test shows changes in the way your liver is working.
- Headaches
- Feeling agitated or irritable
- Feeling more nervous than usual
- Fits
- Feeling drowsy

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