

DOMPERIDONE 10MG 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 domperidone is and what it is used for
2. Before you take domperidone
3. How to take domperidone
4. Possible side effects
5. How to store domperidone
6. Further information

1. WHAT DOMPERIDONE IS AND WHAT IT IS USED FOR

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

Domperidone 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.

Domperidone 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. BEFORE YOU TAKE DOMPERIDONE

Do not take domperidone tablets if:

- You are allergic (hypersensitive) to domperidone or any of the other ingredients of Domperidone 10mg Film-Coated Tablets (listed in section 6: Further 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.

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

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

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

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

Taking other medicines

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 domperidone can affect the way some other medicines work. Also, some medicines can affect the way domperidone works.

Do not use Domperidone 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)

Children:

Do not give domperidone tablets to children who weigh less than 35kg.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking domperidone if:

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

Driving and using machines:

You may feel sleepy, confused or have less control over your movements while taking domperidone. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of domperidone tablets:

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

3. HOW TO TAKE DOMPERIDONE

Always take domperidone 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 domperidone tablets (10 or 20mg) 3 to 4 times a day. Do not take more than 8 tablets (80 mg) in a day.

- **Babies and Children** (over 12 years and who weigh more than 35 kg)
Your doctor will work out the dose depending on the weight of your child. Do not give your child more than 8 tablets (80 mg) in a day. Do not give domperidone tablets to children weighing less than 35kg.

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 domperidone tablets for more than 4 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 domperidone than you should:

- If you have taken more domperidone 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 domperidone:

- If you forget to take domperidone, 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, domperidone can have side effects, although not everybody gets them.

Stop taking domperidone 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 domperidone.
- 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 domperidone.
- 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

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 DOMPERIDONE

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Do not take domperidone 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. FURTHER INFORMATION

What Domperidone 10mg Film-Coated Tablets contain

Each tablet contains 10mg of domperidone (the active ingredient). It also contains lactose, maize starch, microcrystalline cellulose, hypromellose, pregelatinised starch, povidone, propylene glycol, magnesium stearate, silicon dioxide and polysorbate 20.

What Domperidone 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 and Manufacturer

Marketing Authorisation Holder is:

Winthrop Pharmaceuticals, PO Box 611, GU1 4YS, UK

Manufacturer is:

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

This leaflet was last revised in: January 2009

'Winthrop' is a registered trademark © 2009 Winthrop Pharmaceuticals.