

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dompy™ Domperidone 10 mg film-coated tablets

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 Dompy™ is and what it is used for
2. Before you take Dompy™
3. How to take Dompy™
4. Possible side effects
5. How to store Dompy™
6. Further information

1. WHAT DOMPY™ IS AND WHAT IT IS USED FOR

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

Dompy™ 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.

Dompy™ 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 DOMPY™

Do not take Dompy™ tablets if:

- You are allergic (hypersensitive) to domperidone or any of the other ingredients of Dompy™ 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 Dompy™ if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Dompy™.

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

- You have any kidney problems. If you take Dompy™ 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 Dompy™. Do this even if they have applied in the past.

Dompy™ 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. Dompy™ should be used at the lowest effective dose in adults and children.

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

Do not use Dompy™ 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 Dompy™ Tablets to children who weigh less than 35kg.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking Dompy™ if:

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding. It is best not to take Dompy™ 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 Dompy™. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Dompy™ tablets

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

3. HOW TO TAKE DOMPY™

Always take Dompy™ 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 Dompy™ tablets (10 or 20 mg) 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

Dompy™ 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 Dompy™ 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 Dompy™ than you should:

- If you have taken more Dompy™ 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 Dompy™:

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

Stop taking Dompy™ 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 Dompy™.
- 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 Dompy™.
- 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

Dompy™ 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. Dompy™ 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 DOMPY™

- Keep out of the reach and sight of children.
- Do not store above 30 °C.
- Do not take Dompy™ 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 Dompy™ 10mg Film-Coated Tablets contain

Each Dompy™ 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 Dompy™ 10mg Film-Coated Tablets look like and contents of the pack

Tablets: Pack of 3 blisters of 10 tablets each.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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To report any side effect(s):

- Saudi Arabia:
National Pharmacovigilance Center (NPC)
Fax: +966-1-210-7398
E-mail: npc.drug@sfd.gov.sa, Website: www.sfd.gov.sa/npc
- Other GCC States:
– Please contact the relevant competent authority.

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THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
Keep medicament out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



Dompy™ is a quality product manufactured by:



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