

Package leaflet: Information for the user

Dompicare 20 mg film-coated tablets domperidone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- *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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *If you get any side effects, talk to you doctor or pharmacist. This includes any possible side effects not listed in this leaflet.*

What is in this leaflet

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

1. What Dompicare is and what it is used for

This medicinal product contains the active substance domperidone, which belongs to a group of medicines called dopamine antagonists. It works by normalising the movements within your intestines. In adults this medicinal product is used to treat the symptoms of nausea and vomiting, feeling of fullness, stomach discomfort and regurgitation (backflow of the stomach contents in the mouth). In adolescents (aged over 12 and weighing more than 35 kg) this medicinal product is used to treat the symptoms of nausea and vomiting.

2. What you need to know before you take Dompicare

Do not take Dompicare:

- if you are allergic to domperidone or any of the other ingredients of this medicine (listed in section 6),
- if you suffer from a tumour of the pituitary gland called prolactinoma,
- if you have persistent black, tarry stools or severe stomach cramps. This could be signs of internal bleeding or a blockage or tear in the stomach or intestine.

If you have any doubts, ask your doctor or pharmacist for advice.

Warnings and precautions

Talk to your doctor before taking Dompicare.

- If you have impaired liver function.
- If you have impaired kidney function.
- If you have a very fast or unusual heartbeat or any other heart problems (see section 4).

If you have any doubts, ask your doctor or pharmacist for advice.

Children and adolescents

Dompicare is not suitable for use of children under 12 years of age and weighing less than 35 kg.

Other medicines and Dompicare

Tell your doctor if you are taking, have recently taken or might take:

- drugs to treat viral infections (e.g. ritonavir, indinavir, nelfinavir, saquinavir, efavirenz),
- antibiotics for infections (e.g. clarithromycin, erythromycin, rifampicin, telithromycin),
- drugs used to treat fungal infections taken by mouth (e.g. ketoconazole, itraconazole),
- drugs used to treat depression (e.g. nefazodone, St. John's wort),
- drugs used to treat epilepsy (e.g. carbamazepine)
- drugs used to treat heart diseases (e.g. verapamil, quinidine),
- drugs used to reduce stomach acid (e.g. proton pump inhibitors, H2 receptor antagonists, and antacids).

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medication.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this medicine if you are pregnant or breast-feeding unless your doctor has prescribed it for you. Make sure you follow your doctor's prescription closely.

If you discover you are pregnant during treatment, tell your doctor who will decide whether or not you should continue treatment.

Driving and using machines

This medicine does not (or only to a negligible extent) affect your ability to drive or use machines.

Dompicare contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Dompicare

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Adults and adolescents (aged 12 and weighing more than 35 kg)

1/2 tablet (10 mg) to 1 tablet (20 mg), 3 to 4 times a day, without exceeding a total of 4 tablets (80 mg) a day.

Use in children

The film-coated tablets form is not suitable for children under 12 years of age and weighing less than 35 kg.

People with kidney problems

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

Method of administration

To be swallowed.

The tablets should be taken before meals. If you take it after meals, it may take longer to be absorbed by the body.

Tablets can be divided into two equal doses.

Duration of treatment

The initial treatment duration is 4 weeks. If symptoms persist after 4 weeks, your doctor will decide whether or not you should continue taking Dompicare.

Always follow your doctor's prescription closely.

If you take more Dompicare than you should

Immediately tell your doctor or pharmacist.

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 twisted neck).

If you forget to take Dompicare

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

- You get an allergic reaction (very rare)
Symptoms may include 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).
- You notice uncontrolled movements (very rare)
Symptoms may 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 Dompicare tablets.
- You have a very fast or unusual heartbeat (unknown frequency)
This could be a sign of a life-threatening heart problem.

Other side effects include:

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

- Increase in prolactin levels (hormone inducing milk flow)
- Galactorrhea (milk flow outside periods of breastfeeding)
- Gynecomastia (abnormal breast development in men)
- Amenorrhea (periods become irregular or stop)
- Gastrointestinal disorders including very rare and transient intestinal cramps

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

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

Unknown frequency (cannot be estimated from available data)

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

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.

5. How to store Dompicare

This medicinal product does not require any special storage condition.
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dompicare contains

- The active substance is domperidone.
Each film-coated tablet contains 20 mg of domperidone.
- The other ingredients are:
Core: Lactose monohydrate, povidone, maize starch, crospovidone, sodium laurilsulfate, microcrystalline cellulose, hydrogenated castor oil, magnesium stearate
Coating: hypromellose.

What Dompicare looks like and contents of the pack

Dompicare are white, oblong and biconvex film-coated tablets with a score line on one face.
Dompicare is available in packs containing 10, 20, 30, 40, 60 and 100 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in 17/04/2013.