

Patient Information Leaflet

DAFRAZOL®

Omeprazole 20 mg, gastro-resistant capsules

Read all of this leaflet carefully before you start using 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.

1. What is Dafrazol® and what it is used for

Dafrazol® contains the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces. (ATC-code: A02BC01). Dafrazol® is used to treat the following conditions: 'Gastro-oesophageal reflux disease' (GORD) (where acid from the stomach escapes into the gullet causing pain, inflammation and heartburn); ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer); ulcers which are infected with bacteria called '*Helicobacter Pylori*'; ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs); too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

In children over 1 year of age and ≥ 10 kg: GORD; in children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

Children and adolescents over 4 years of age: ulcers which are infected with bacteria called '*Helicobacter Pylori*'.

2. What you need to know before you take Dafrazol®

You must not take Dafrazol® if you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6); if you are allergic to other proton pump inhibitor medicines (e.g. antoprazole, lansoprazole, rabeprazole, esomeprazole); if you are taking nelfinavir (for HIV infection). **Warnings and precautions:** Dafrazol® may hide the symptoms of other diseases.

Therefore, if any of the following happen to you before you take Dafrazol® or after you have taken it, tell it immediately to your doctor: you lose a lot of weight for no reason and have problems swallowing; you get stomach pain or indigestion; you begin to vomit food or blood; you pass black stools; you experience severe or persistent diarrhoea, you have severe liver problems. If you take a proton pump inhibitor like Dafrazol® for more than one year, you may slightly increase the risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Other medicines and Dafrazol®: Like all antacids Dafrazol can delay the absorption of other drugs. Tell your doctor, nurse or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines that you buy without a prescription. This is because Dafrazol® can affect the way some medicines work and some medicines can have an effect on Dafrazol® IV. Tell your doctor, nurse or pharmacist if you are taking any of the following medicines: ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus); digoxin (used to treat heart problems); diazepam (used to treat anxiety, relax muscles or in epilepsy); phenytoin (used in epilepsy); medicines that are used to thin your blood, such as warfarin or other vitamin K blockers; rifampicin (used to treat tuberculosis); atazanavir (used to treat HIV infection); tacrolimus (in cases of organ transplantation); St John's wort (*Hypericum perforatum*) (used to treat mild depression); cilostazol (used to treat intermittent claudication); saquinavir (used to treat HIV infection); clopidogrel (used to prevent blood clots); erlotinib (used to treat cancer); methotrexate (a chemotherapy medicine used in high doses to treat cancer). If your doctor has prescribed the antibiotics amoxicillin and clarithromycin in combination with Dafrazol® to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking. **Pregnancy and breastfeeding:** if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine. Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used. **Driving and using machines:** Dafrazol® is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

3. How to take Dafrazol®

Always take Dafrazol® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. **Your doctor will tell you how many capsules to take, and how long to take them for.** This will depend on your condition and how old you are.

It is recommended that you take your capsules in the morning, with food or on an empty stomach. Swallow your capsules whole with half a glass of water. Do not chew or crush the capsules: it is important not to damage the pellets.

If you have taken more Dafrazol® than it should, then contact your doctor as soon as possible. **If you forgot to take a dose,** take it as soon as you remember it. However, if it is almost time for your 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, Dafrazol® can cause side effects, although not everybody gets them. **If you notice any of the following rare but serious side effects, stop using Dafrazol® and contact a doctor immediately:** sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (symptoms of a severe allergic reaction); reddening of the skin with blisters or peeling (possible symptoms of 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'); yellow skin, dark urine and tiredness (possible symptoms of liver problems). **Common side effects (1 in 10 people):** headache; effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence); feeling sick (nausea) or being sick (vomiting). **Uncommon side effects (1 in 100 people):** swelling of the feet and ankles; disturbed sleep; dizziness, tingling feelings such as "pins and needles", feeling sleepy; spinning feeling (vertigo); changes in blood tests that check how the liver is working; skin rash, lumpy rash (hives) and itchy skin; generally feeling unwell and lacking energy. **Rare side effects (1 in 1,000 people):** blood

problems such as a reduced number of white cells or platelets (possible cause for weakness, bruising or make infections more likely); allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing; low levels of sodium in the blood (possible cause for weakness, being sick (vomiting) and cramps); Feeling agitated, confused or depressed; taste changes; eyesight problems such as blurred vision; suddenly feeling wheezy or short of breath; dry mouth; inflammation of the inside of the mouth; an infection called “thrush” which can affect the gut and is caused by a fungus; liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness; hair loss; skin rash on exposure to sunshine; joint pains or muscle pains; severe kidney problems; increased sweating. **Very rare side effects (may affect up to 1 in 10,000 people):** changes in blood count including lack of white blood cells; aggression; seeing, feeling or hearing things that are not there (hallucinations); severe liver problems leading to liver failure and inflammation of the brain; sudden onset of a severe rash or blistering or peeling skin (may be associated with a high fever and joint pains); muscle weakness; enlarged breasts in men. **Not known frequency:** inflammation in the gut (leading to diarrhoea).

Your doctor may decide to perform regular blood tests to monitor your levels of magnesium, because if you are on Dafrazol® for more than three months it is possible that the levels of magnesium in your blood may fall, giving fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. Irreversible visual impairment has been reported in isolated cases of critically ill patients who have received omeprazole especially at high doses. In very rare cases Dafrazol® may affect the white blood cells: if you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection (pain in the neck, throat or mouth or difficulties in urinating), you must consult your doctor as soon as possible. **If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.**

5. How to store Dafrazol®

Store below 25°C, in the original package, protected from light and humidity. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month. .

6. Other information

What Dafrazol® contains: Each gastro-resistant capsule contains 20 mg Omeprazole as enteric coated micro pellets. Other ingredients of the pellets: Sugar spheres, Sodium starch glycolate, Sodium laurilsulfate, Povidone, Hypromellose phthalate, Sucrose, Hypromellose, Mannitol, Diacetylated monoglycerides, Talc. The hard gelatin capsule contains titanium dioxide E171, red iron oxide E172, quinoline yellow E104, indigo carmine – FD&C Blue 2 (E132).

Dafrazol® is presented as green opaque/yellow opaque capsules in a box with 14 capsules in 2 blisters or 28 capsules in 4 blisters..

Dafrazol® is a prescription only medicine.

Name of Manufacturer

Registration/Licence Holder

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