

Patient Information Leaflet

DAFRAZOL®

Omeprazole 20 mg , gastro-resistant capsule

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you have questions or you notice side effects not mentioned in this leaflet, contact your doctor or your healthcare professional. Do not pass this medicine on to others.

1. What Dafrazol is 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

Do not take Dafrazol if

- you are allergic (hypersensitive) to omeprazole or to any other ingredient of this medicine listed in section 6.
- you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole)
- you are taking nelfinavir (for HIV infection).

Warnings and precautions

Dafrazol may hide the symptoms of other diseases. Therefore, if any of the following happens 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 medicines.

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines without a prescription. This is because Dafrazol can affect the way some medicines work and some medicines can have an effect on Dafrazol.

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 breast-feeding

If you think you might be pregnant, or are planning to get pregnant or if you are breast-feeding, you must tell your doctor that you are taking medicines.

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 machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

Important information about some ingredients of Dafrazol

The micro pellets in the capsules of Dafrazol contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Dafrazol

Always take Dafrazol exactly as your doctor has told you.

Your doctor will tell you how many capsules to take, and how long to take these.

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 take more Dafrazol than you should

then contact your doctor as soon as possible.

If you forget to take a dose

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5. How to store Dafrazol

Keep out of the reach and sight of children.

Store below 30°C, in the original package to protect from light and humidity.

Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and further information

What Dafrazol contains

Each gastro-resistant capsule contains 20 mg of omeprazole as enteric coated micro pellets.

The other ingredients are 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).

What Dafrazol looks like and content of the pack

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 medicine.

Manufacturer

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Marketing Authorisation Holder

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