

Dafrazol[®] IV

omeprazole

POWERFUL INTRAVENOUS TREATMENT OF:

Gastric and / or duodenal ulcers,
Gastroesophageal reflux

RAPID AND PROLONGED DECREASE OF INTRAGASTRIC ACIDITY

POSODOLOGY

1 intravenous injection of DAFRAZOL[®] IV 40 mg / day.

*After reconstitution the injection should be administered slowly
in minimum 2.5 minutes (max 4 ml / min).*

DAFRA PHARMA INTERNATIONAL

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Setting the Standard

www.dafrapharma.com

Dafrazol® IV

omeprazole



THE REFERENCE PPI WHEN INTRAVENOUS ADMINISTRATION IS PREFERRED

POWERFUL TREATMENT OF:

Gastric ulcers

Duodenal ulcers

Gastroesophageal reflux



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WHAT IS DAFRAZOL[®] I.V. AND WHAT IT IS USED FOR?

DAFRAZOL[®] I.V. 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. **DAFRAZOL[®] I.V.** powder and solvent for solution for injection can be used as an alternative to oral therapy (ATC-code: A02BC01).

WHAT YOU NEED TO KNOW BEFORE DAFRAZOL[®] I.V. IS GIVEN TO YOU?

You must not be given DAFRAZOL[®] I.V. if you are allergic to omeprazole or any of the other ingredients of this medicine; 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[®] I.V. may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you are given **DAFRAZOL[®] I.V.** or after you are given 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[®] I.V.** 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[®] I.V.: Like all antacids **DAFRAZOL[®] I.V.** 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[®] I.V.** can affect the way some medicines work and some medicines can have an effect on **DAFRAZOL[®] I.V.** 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[®] I.V.** 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[®] I.V. 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. If affected, you should not drive or operate machinery.

HOW DAFRAZOL[®] I.V. IS GIVEN TO YOU

DAFRAZOL[®] I.V. will be given to you as an injection into one of your veins, by a doctor who will decide how much you need. **DAFRAZOL[®] I.V.** can be given to adults. There is limited experience with **DAFRAZOL[®] I.V.** for intravenous use in children. If you are given more **DAFRAZOL[®] I.V.** than it should, then contact your doctor as soon as possible.

POSSIBLE SIDE EFFECTS

Like all medicines, **DAFRAZOL[®] I.V.** can cause side effects, although not everybody gets them. **If you**

notice any of the following rare but serious side effects, stop using DAFRAZOL® I.V. 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® I.V.** 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 **DAFRAZOL® I.V.** especially at high doses. In very rare cases **DAFRAZOL® I.V.** 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.**

HOW TO STORE DAFRAZOL® I.V.:

Store below 30°C. Keep the containers in the outer carton in order to protect from light. Reconstituted solution: chemical and physical in-use stability has been demonstrated for 4 hours at room temperature (25°C) and for 12 hours refrigerated (2°C – 8°C) after reconstitution. From a microbiological point of view, the product should be used immediately unless it has been reconstituted under controlled and validated aseptic conditions.

WHAT DAFRAZOL® I.V. CONTAINS:

Each vial of powder for solution for injection contains Omeprazole Sodium 42.6 mg, equivalent to Omeprazole 40 mg. After reconstitution, 1 ml contains Omeprazole Sodium 4.26 mg, equivalent to Omeprazole 4 mg. Other ingredients: Sodium Hydroxide (in powder vial). Ampoule of solvent: Citric Acid Monohydrate, Macrogl 400, water for injections.

DAFRAZOL® I.V. is presented in a pack consisting of a glass vial containing lyophilized powder and a glass ampoule containing solvent for intravenous administration.

DAFRAZOL® I.V. IS A PRESCRIPTION ONLY MEDICINE.



For the complete SMPC, please visit www.dafrapharma.com