Dafrazol®

omeprazole

Powerful treatment of duodenal and gastric ulcers

ADULTS	
Treatment and prevention of relapse of duodenal ulcer Treatment and prevention of gastric ulcer Treatment of reflux oesophagitis	20 mg to 40 mg / day
Eradication of H. pylori in peptic ulcer	20 mg + appropriate antibiotics 2 x / day for 7 days
Treatment and prevention of gastric and duodenal ulcers associated with NSAIDs	20 mg / day in 1 take
Long term management of patients with healed reflux esophagitis	10 mg to 40 mg / day
Treatment of symptomatic gastrooesophageal reflux disease	10-20 mg / day
Treatment of Zollinger-Ellison syndrome	Initial dose 60 mg / day Maintenance dose 20 to 120 mg / day
CHILDREN (> 1 year and ≥ 10 kg)	
Treatment of reflux oesophagitis	10-20 kg: 10 mg / day
Symptomatic treatment of heartburn and acid regurgitation in gastro esophageal reflux disease	> 20 kg: 20 mg / day

DAFRA PHARMA INTERNATIONAL

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Dafra PHARMA

Setting the standard

www.dafrapharma.com

Dafrazol®

omeprazole

EUROPEAN GMP

POWERFUL TREATMENT OF DUODENAL AND GASTRIC ULCERS

Microgranules with enteric coating for a better action

Also indicated for the treatment of reflux oesophagitis

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MICROGRANULES WITH ENTERIC COATING

PRESENTATION

- Box of 14 capsules distributed in two blisters containing 7 capsules each. Each capsule contains 20 mg of omeprazole in the form of microgranules with gastro-resistent coating.
- Box of 28 capsules distributed in four blisters containing 7 capsules each. Each capsule contains 20 mg of omeprazole in the form of microgranules with gastro-resistent coating.

INDICATIONS

In adults

- Eradication of Helicobacter pylori in the case of ulcerative gastroduodenal disease and inassociation with an antibiotic bitherapy.
- Evolutionary duodenal ulcer.
- Evolutionary gastric ulcer.
- Ulcerative or erosive esophagitis symptoms for gastroesophageal reflux.
- Symptomatic treatment of gastroesophageal reflux disease.
- Zollinger-Ellison Syndrome
- Treatment of gastroduodenal lesions induced by non-steroidal anti-inflammatory drugs.

In children over one year old

Ulcerative or erosive esophagitis symptoms due to gastroesophageal reflux.

CONTRA-INDICATIONS

- Hypersensitivity to one of the components of this medication.
- Due to the presence of sucrose, this medication is contraindicated in case of intolerance to fructose, glucose and galactose malabsorption syndrome or saccharase-isomaltase deficiency.
- Due to the transmission of omeprazole inbreast milk, breastfeeding should be avoided.

WARNINGS

As with other gastric anti-secretores, omeprazole favours the development of intragastric bacteria by decreased volume and acidity of gastric juice.

PRECAUTIONS

- In case of gastric ulcer, it is recommended to check the benignity of the lesion before treatment.
- Elderly: No dosage adjustment is required.
- Kidney failure: There is no significant change in the bioavailability of omeprazole.
- Liver failure: the area under the curve is increased and the elimination is delayed; adose of 20 mg of Dafrazol® is usually enoughin these patients.
- Pregnancy: animal studies did not reveal any teratogenic effect. Therefore, the use of Dafrazol® should only be considered during pregnancy when needed.

INTERACTION WITH OTHER MEDICINAL PRODUCTS

The decrease of intragastric acidity canalter the absorption of certain medications. Thus, it is expected that the absorption of ketoconazole and itraconazole reduces during treatment with omeprazole, in the same way it decreases with other anti-secretors or antacid agents. Since omeprazole is metabolized by the cytochrome P450 liver system (CYP) it is possible for interactions with substances that use the same metabolic pathway to take place:aminopirine, antipyrine, clopidogrel, diaze-pam,phenytoin, warfarin (or other vitamin K antagonists), theophylline, voriconazole, propranolol, metoprolol, lidocaine, quini-dine,ethanol, piroxicam, diclofenac and naproxen.

UNDESIRABLE EFFECTS

Omeprazole is well tolerated. Most side effects reported were mild and transient and did not provide consistent liaison with the treatment. Some cases of nausea, diarrhoea, flatulence, constipation, rashes and headache have been reported.

DOSAGE AND METHOD OF ADMINISTRATION

The capsules can be swallowed during a meal oron an empty stomach.

In adults

- **Eradication of Helicobacter pylori** on gastroduodenal ulcerative disease: the following posology is recommended:
  * Take 1 capsule of Dafrazol® 20 mg morning and evening with clarithromycin 500 mg morning and evening and amoxicillin 1000 mgmorning and evening, for 7 days;
  * Take 1 capsule of Dafrazol® 20 mg morning and evening with clarithromycin 500 mg morning and evening and metronidazole or tinidazole 500 mg morning and evening, for 7 days. This triple therapy is followed by 20 mg of Dafrazol® a dayfor 3 additional weeks in case of duodenal ulcer, or 3 to 5 weeks in case of evolving gastric ulcer.
- **Evolving duodenal ulcer:** 1 capsule Dafrazol® 20 mg daily for 4 weeks.
- **Evolving gastric ulcer:** 1 capsule of Dafrazol® 20 mg daily for 4 to 6 weeks.
- **Esophagitis by gastroesophageal reflux:** 1 capsule of Dafrazol® 20 mg daily for 4 weeks with a possible second period of 4 weeks with the same dosage. In case of severe esophagitis(circumferential ulcers), an increase can be proposed to 40 mg of Dafrazol® in 2 doses in the absence of healing and/or in case of persistence of symptoms at the end of an initial 4 weeks of treatment with the dosage of 20 mg/day.
- **Symptomatic treatment of gastro-esophagealreflux disease:** The dosage is 1 capsule per day.The initial treatment is 4 to 6 weeks. After that, it may be administered as an intermittent treatment during the symptomatic periods.
- **Zollinger-Ellison syndrome:** the recommended initial dosage is 60 mg of Dafrazol® once aday. The dosage must be adjusted individually and the treatment shall continue in the longterm, as medically necessary. For dosages over 80 mg per day, the daily dose should be divided and taken in 2 doses.
- **Treatment of gastroduodenal lesions inducedby nonsteroidal anti-inflammatory drugs:** 1 daily capsule of Dafrazol® 20 mg for 4 to 8 weeks.

In children over 20 kg

Gastroesophageal reflux disease: 1 capsule Dafrazol® 20 mg daily for 4-8 weeks. For children under 6 years (due to the risk of aspiration) and children unable to swallow capsules, the capsules should be opened and mixed with mildly acidic foods (pH<5), such as: yogurt, orange juice, apple sauce ...

PHARMACODYNAMICS

Omeprazole reduces gastric acid secretion through a highly selective mechanism of action. It creates a specific and dose dependent inhibition of the enzyme in the parietal cells of the stomach. This enzyme H+,K+ ATPase, known as the protonpump is responsible for the acid secretion by the parietal cell. Since this inhibition occurs at the initial stage of the process, there is selective inhibition of the basal and of stimulated gastric secretion, irrespective of the stimulus used to provoke acid secretion. Omeprazole has no effects on acetylcholine or histamine receptors. The drug is devoid of other pharmacodynamic action. Reduction of acid secretion is profound and lasts for about 24 hours. The onset of action is rapid and the process is completely reversible after stopping the therapy. The single daily dose of 20 mg Dafrazol® orally causes a rapid and effective inhibition of gastric acid secretion. The maximum effect is obtained in 4 days of treatment. In patients with duodenal ulcer, an average decrease of about 80% of gastric acidity in 24 hours is maintained. The healing rates of duodenal ulcer varies between 65% at two weeks and 95% at four weeks. Eradication of Helicobacter pylori is associated with healing and prolonged remission of peptic ulcer disease.

PHARMACOKINETICS

- A mean decrease of at least 80% in 24-hour intragastric acidity.
- With the mean decrease in peak acid output being about 70% 24 hours after dosing.
- Rapid absorption with peak plasma levels occurring approximately 1-2 hours afterdose.
- Plasma protein binding: 97%.
- Plasma elimination half-life: < 1h.
- Elimination: approx 80% is excreted as metabolites in the urine the remainder in the faeces. Presence of 2 metabolites in urine:
  - **Hydoxy-oméprazole**
  - **L'acide carboxylique correspondant.**

STORAGE CONDITIONS

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.