DANLOX® QUICK

OMEPRAZOLE SODIUM BICARBONATE

ORAL SUSPENSION POWDER

Expended under prescription
Made in Argentina

Formula
Each pack contains: omeprazole 20 mg; sodium bicarbonate 1.680,0 mg. Excipients: colloidal silica dioxide 30,0 mg; sugar 2.585,0 mg; sucralose 85,0 mg; sodium alginate 100,0 mg; corn starch 100,0 mg; sodium hydroxide q.s. pH 11,0-12,5; banana essence 400,0 mg.

Therapeutic Action: Inhibitor of gastric acid secretion - antiulcerous drug.

Indications: Treatment of active duodenal ulcer, gastric ulcer, symptomatic gastroesophagic reflux, erosive esophagitis diagnosed by endoscopy. Maintenance treatment of healed erosive esophagitis.

Pharmacological Action: Omeprazole inhibits gastric acid secretion by inhibition of Hydrogen/ Potassium ATPase ("Proton Bomb") of gastric parietal cells. Its action is fast, and a single daily dose produces a reversible control of gastric acid secretion. It inhibits both baseline acid secretion and stimulated acid secretion. Omeprazole is rapidly degraded by gastric acid. The sodium bicarbonate contained in DANLOX QUICK increases gastric pH and so protects omeprazole from acid degradation, thus enhancing its bioavailability.

Pharmacokinetics: Absorption: Omeprazole is rapidly absorbed when administered on an empty stomach one hour before meals. If administered together with or after meals, the area under the curve is reduced by 24%. The maximum plasma concentration is reached after around 30 minutes. Omeprazole is bound to plasma proteins in 95%. Most of the dose (77%) is eliminated in the urine in the form of six metabolites, two of them being hydroxyomeprazole and a carboxylic acid. The rest of the dose administered is excreted in the feces. Three omeprazole metabolites having little antisecretory activity have been identified in plasma. The excretion of unaltered drug is virtually null. Omeprazole half-life is of about 1 hour. Geriatric Use: Elimination of the drug is reduced in the elderly population, its bioavailability increasing (from 58% to 76%). Pediatric Use: The pharmacokinetics of the drug have not been studied in patients under 18 years of age. Hepatic Failure: In these cases, bioavailability increases to 100% and half-life is 3 hours, thus reflecting the diminished hepatic metabolism of omeprazole. Renal Failure: In these cases, urinary elimination of omeprazole metabolites is diminished.

Posology
- *Short-term treatment of duodenal ulcer:* 20 mg once a day for 4 weeks. Some patients require 4 additional weeks.
- *Treatment of gastric ulcer:* 40 mg once a day for 4 to 8 weeks.
- *Symptomatic gastroesophagic reflux:* 20 mg once a day for 4 weeks.
- *Erosive esophagitis:* 20 mg a day for 4-8 weeks. Its efficacy after 8 weeks of dosage has not been established.
- *Maintenance treatment of healed erosive esophagitis:* 20 mg a day. The duration of the carried out controlled studies was less than 12 months.

Administration Mode
Adults
• DANLOX QUICK Oral Suspension Powder should be taken with an empty stomach.
• DANLOX QUICK Oral Suspension Powder is supplied in single-dose packs containing omeprazol 20 mg and sodium bicarbonate 1.680 mg in an immediate release formulation.
• Pour the pack content in a small vessel with not less than two tablespoons of WATER (20 ml). DO NOT USE OTHER LIQUIDS OR FOODS.
• Mix well and take immediately.
• Put some water again in the vessel and drink the content.
Preparation of a suspension for paediatric use
The total daily dose may be administered in 1 or 2 intakes.
• Place in a vessel 17 ml of water (for calculation it is suggested to use for example a 20 mL-syringe).
• Add the content of a pack and stir well.
• Thus, 20 ml of suspension will be obtained with 1 mg of omeprazol per millilitre.
• Measure (for example with a 20 mL-syringe) the millilitre quantity indicated by the physician, separate and

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administer orally (directly or diluted in water, as appropriate).
• The non-used prepared amount of suspension may be stored in refrigerators, during 24 hours. Stir or mix well the suspension which is stored in the refrigerator before each use.

Contraindications: Hypersensitivity to omeprazole or any of the formula components.

Warnings: The favorable evolution of the symptoms with the treatment does not rule out the presence of stomach cancer, so the lesion should be confirmed to be benign before therapy initiation. In patients under long-term treatment with omeprazole, there have been occasional cases of gastric atrophy.

Precautions:
- *Patients with renal disorders:* Dose adjustment is not necessary in these patients.
- *Patients with liver disorders:* An increased plasma half-life of omeprazol is produced in these cases, so it is possible to require a dosage adaptation.
- *Geriatric patients:* special precaution due to sodium supplementation.
In pharmacosurveillance studies carried out in geriatric patients who were extended dosed with proton pump inhibitors, and particularly with high doses, a slight increase of the bone fracture frequency was observed. Therefore, special control in long-term use of these products is advised.

Drug Interactions: The decreased intragastric acidity may modify the absorption of some drugs. Ketoconazole decreases its absorption during treatment with omeprazole or other inhibitors of acid secretion, as well as ampicillin esters and iron salts. As omeprazole is metabolized at hepatic level by the P450 cytochrome, it may prolong the half-life of diazepam, warfarin, phenytoin, cyclosporine, and disulfiram, so patients who receive these drugs should be controlled in case they need an eventual reduction of the dose.
Plasma concentrations of omeprazole and clarythromycin are increased when they are supplied concomitantly.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In two 24-month studies carried out in rats and using a dose of omeprazole 4 to 352 times higher than the dose used in human beings, carcinoid tumors of enterochromaffin gastric cells were dose-dependently observed. In addition, hyperplasia of enterochromaffin cells was observed in all treated groups. In other studies on carcinogenesis, no increased incidence of these tumors was observed. Omeprazole did not show mutagenic characteristics in in vitro studies and did not produce impairment of fertility in experimental animals, even at doses 35 to 345 times higher than those used in human beings.
Pregnancy and Lactation: Omeprazol should only be administered to pregnant women if considered essential. Animal studies up to date have not shown damage caused by omeprazole administered during pregnancy and lactation, nor evidence of fetal toxicity or teratogenic effects. In human beings, doses up to 80 mg have been administered for 24 hours to women in labor without adverse reactions in newborns.
Pediatric Use: The safety and efficacy of omeprazole in pediatric patients have not been established.
Geriatric Use: Although no dose adjustment is necessary in the elderly population, the impact of the additional sodium intake and increased sensitivity should be considered in some cases.

Adverse Reactions
Omeprazole is usually well tolerated and adverse reactions are mild. The following adverse effects have been described:
- Skin: Rarely, rash or pruritus; isolated cases of photosensitivity, multiform erythema, and alopecia.
- Musculoskeletal: Arthralgias, myalgias, cramps, and muscle weakness have been rarely described.
- Central and Peripheral Nervous System: Occasionally migraines and dizziness; in isolated cases depression, agitation, mental confusion, and hallucinations have been described.
- Gastrointestinal System: Constipation, diarrhea, nausea, and/or vomiting, flatulence and abdominal pain. In isolated cases, dry mouth, stomatitis, and gastrointestinal candidiasis.
- Hepatic: An increase in hepatic enzymes has been very rarely observed. In isolated cases, in patients with preexisting severe hepatic disease, hepatitis, encephalopathy, and hepatic failure have been observed.
- Endocrine: Gynecomastia in isolated cases.
- Hematological: Leukopenia, thrombocytopenia, agranulocytosis, and pancytopenia have been rarely described.
- Respiratory System: Epistaxis and pharyngeal pain have been rarely described.
- Cardiovascular System: Chest pain, tachycardia, bradycardia, palpitations, blood hypertension.
- Urogenital: Urinary infection, pollakiuria, microscopic pyuria, testicular pain, proteinuria, hematuria, glucosuria, serum creatinine increase.
- Metabolic: Hyperglycemia and weight gain.
- Other types of adverse effects: General discomfort, hypersensitivity reactions (urticaria, angioedema, fever, bronchospasm, interstitial nephritis) and anaphylactic shock), hyperhydrosis, peripheral edema, blurred vision, dysgeusia, etc.

Overdosage: There may be cases of blurred vision, sweating, dry mouth, headache, reddening, tachycardia, nausea, confusion, and somnolence. Treatment should be symptomatic and of clinical support. Omeprazole is not dialyzable since it is highly bound to plasma proteins.
In the event of an overdosage, go to the nearest Hospital or contact the Toxicology Center at:
Hospital A. Posadas: (011) 4654-6648/4658-7777.
Hospital de Pediatría Ricardo Gutierrez: (011) 4962-6666/2247.
Optionally other Toxicology Centers.

How-Supplied: Packages containing 15 monodoses.

Storage:
- Store protected from heat (<30ºC) and excessive humidity.
- Keep out of the reach of children.

Technical Direction: Dr. Luis M. Radici – Pharmacist
PHARMACEUTICAL PRODUCT AUTHORIZED BY THE MINISTRY OF HEALTH.
Certificate No. 54.182
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