RAZON®

DESCRIPTION

RAZON is the trade name of Pantoprazole, a proton pump inhibitor.

Each **RAZON** 40 mg Enteric-Coated Tablet contains Pantoprazole 40 mg as Pantoprazole Sodium.

CHEMISTRY

Pantoprazole Sodium is: 5-(Difluoromethoxy)-2-[[(3,4-dimethoxy-2-pyridinyl)-methyl]sulfinyl]-1H-benzimidazole sodium sesquihydrate salt.

Clinical Pharmacology

RAZON is an antiulcer drug. It is a specific inhibitor of the proton pump of H^+/K^+ ATPase, the enzyme responsible for the secretion of acid by the gastric parietal cells. By virtue of its mechanism of action on the terminal phase of secretion, **RAZON** provokes a durable inhibition of basal and stimulated gastric acid secretion. Its action is independent of the nature of the stimulus.

RAZON is administered in the form of Enteric-Coated Tablets because Pantoprazole is destroyed in the acidic medium. After oral administration, the absolute bioavailability of Pantoprazole is 70-80%. Pantoprazole is very weakly dialysable.

INDICATIONS

- ☐ Progressive duodenal ulcer.
- ☐ Progressive gastric ulcer.
- ☐ Esophagitis due to gastroesophageal reflux, confirmed endoscopically by existing erosions or ulcerations.

DOSAGE

Usual adult dose

- ☐ Duodenal Ulcer: One **RAZON** 40 mg Tablet once daily, before or during breakfast. Treatment for 4 weeks is usually sufficient.
- ☐ Gastric Ulcer: One **RAZON** 40 mg Tablet once daily, before or during breakfast. Treatment is usually necessary for 4 weeks; however, treatment may be prolonged to 8 weeks.
- ☐ Esophagitis due to gastroesophageal reflux: One **RAZON** 40 mg Tablet once daily, before or during breakfast. Treatment is usually necessary for 4 weeks, however; treatment may be prolonged to 8 weeks depending on endoscopic results.

Note

RAZON Tablet should not be crushed or chewed; it should be swallowed whole with some water.

Usual pediatric dose

Safety and efficacy of Pantoprazole in children have not been established yet.

ADVERSE EFFECTS

Pantoprazole is well tolerated. Only rarely, cases of cephalgia, diarrhea, pruritus, cutaneous rash, and vertigo have been reported. In addition, these effects where usually transient and of moderate intensity, not requiring cessation of treatment.

USE IN PREGNANCY

Safety of Pantoprazole has not been established in pregnant women.

Animal studies did not demonstrate any teratogenic or fetotoxic effects. However, in common with all new medications, use of Pantoprazole is not advised during the first trimester. The drug should not be used during the second and third trimesters, except if absolutely necessary.

USE IN LACTATION

It is not known whether Pantoprazole is excreted in human breast milk. Accordingly, use is contraindicated in lactating women.

INTERFERENCE WITH CLINICAL AND LABORATORY TESTS

Not documented.

DRUG INTERACTIONS

Limited studies revealed no evidence of interaction between Pantoprazole and antipyrine, diazepam, digoxin, nifedipine, phenytoin, theophylline, warfarin, phenprocoumon, diclofenac or caffeine.

CONTRAINDICATIONS

Pantoprazole is contraindicated in lactating women (see Use In Lactation).

WARNINGS

Risk-benefit should be considered in case of hepatic insufficiency because the half-life of Pantoprazole is prolonged in cirrhotic patients. The recommended dose is one **RAZON** 40 mg Tablet every 2 days in such cases.

OVERDOSE

Doses of up to 240 mg Pantoprazole are well tolerated. There is no specific antidote, and no measures other than symptomatic treatment may be recommended.

PRECAUTIONS

- ☐ No dosage adjustment is necessary in severe renal insufficiency.
- ☐ There is no need for dosage adjustment in geriatrics.
- ☐ In common with other gastric secretion inhibitors, Pantoprazole may favor the development of intragastric bacteria by lowering the volume and acidity of gastric juice.

PRESENTATIONS

- ☐ Boxes of 14 blistered or stripped tablets of **RAZON** 40 mg Enteric-Coated Tablets.
- ☐ Hospital packs of different presentations.

THIS IS A MEDICAMENT

- ☐ A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- ☐ Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- ☐ The doctor and the pharmacist are experts in medicine.
- ☐ Do not by yourself interrupt the period of treatment prescribed for you.
- ☐ Do not repeat the same prescription without consulting your doctor.
- ☐ Keep medicaments out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

Prescribing Information Available Upon Request

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