Panoral®

Pantoprazole Enteric Coated Tablet

DESCRIPTION

Panoral® is a substituted benzimidazole, which inhibits the secretion of hydrochloric acid in the stomach by specific action on the proton pumps of the parietal cells. Pantoprazole is converted to its active form in the acidic canaliculi of the parietal cells when it inhibits the H^+, K^+-ATPase enzyme, i.e. the final stage in the production of hydrochloric acid in the stomach. The inhibition is dose-dependent and affects both basal and stimulated acid secretion. Pantoprazole is rapidly absorbed and the maximal plasma concentration is achieved even after a single oral dose. On an average at about 2.0 h - 2.5 h p.a. the maximum serum concentrations of about 1 - 1.5 µg/mL (**Panoral®** 20 mg) and 2 - 3 µg/mL (**Panoral®** 40 mg) are achieved. Serum protein binding of Pantoprazole is about 98%. The substance is almost exclusively metabolized in the liver and about 80% is eliminated through urine as metabolites, the rest are excreted with the faeces.

INDICATIONS

Panoral® is indicated for-

> Duodenal ulcer
> Gastric ulcer
> Gastro-esophageal reflux disease (GERD)
> Reflux esophagitis
> For the treatment of mild reflux disease and associated symptoms (e.g. heartburn, acid regurgitation, pain on swallowing)
> Zollinger-Ellison Syndrome
> Eradication of Helicobacter pylori (in combination with antibiotics)
> Prevention of gastro-duodenal ulcers induced by non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in patients at risk with a need for continuous NSAID treatment.

DOSAGE AND ADMINISTRATION

Panoral® should be taken orally (40 mg) preferably in the morning with or without food. The duration of the treatment may vary from 2 to 8 weeks.

Duodenal Ulcers: 40 mg once daily for 2-4 weeks

Gastric Ulcers: 40 mg once daily for 4-8 weeks

Reflux esophagitis: 40 mg once daily for 4-8 weeks

Zollinger-Ellison Syndrome: 40 mg once daily. Once control of acid secretion has been established, the dose should be gradually reduced to the lowest effective dose.

Eradication of Helicobacter pylori: Triple therapy of Pantoprazole 40 mg twice daily with appropriate antibiotic.

Ulcers induced by NSAIDs: 40 mg once daily as long as the patient continues his/her treatment with NSAID.

Use in children: There are no data currently available on the use of pantoprazole in children.

Use in elderly: The daily dose of 20 mg or 40 mg can be given.

Impaired Renal Function: The daily dose of 20 mg or 40 mg can be given.

Impaired Liver Function: In patients with severe liver impairment the dose has to be reduced to 20 mg pantoprazole per day.

CONTRAINDICATIONS

Pantoprazole tablet is contraindicated in patients with known hypersensitivity to it or to any component of the formulation.

USE IN PREGNANCY AND LACTATION

No data are available on administration of Pantoprazole to pregnant and lactating women. However this drug should be used, only if clearly needed.

SIDE-EFFECTS

Pantoprazole is generally well tolerated. Nausea, headache, abdominal pain, diarrhoea, constipation or flatulence have been reported in some isolated cases. Allergic reactions such as pruritus and skin rash have occurred in few patients. These events have usually been mild and transient and there has been no consistent relationship with treatment.

DRUG INTERACTIONS

Pantoprazole is metabolized through the cytochrome P-450 system, and subsequently undergoes Phase II conjugation. Based on studies evaluating possible interactions of Pantoprazole with other drugs metabolized by the cytochrome P-450 system, no interaction has been observed and no dosage adjustment is needed with concomitant use of the following drugs; theophylline, antipyrine, caffeine, carbamazepine, diazepam, diclofenac, digoxin, ethanol, glyburide, an oral contraceptive (Levonorgestrel/ethinyl estradiol), metoprolol, nifedipine, phenytion or warfarin. There was also no interaction with concomitantly administered antacids and food.

OVERDOSAGE

There are no known symptoms of over dosage in man. In the case of over dosage with clinical signs of intoxication, the usual rules of intoxication therapy apply.

PHARMACEUTICAL PRECAUTION

Store in a dry place. Keep out of reach of children.

PACKAGING

Panoral® 20 tablet: Box containing 4 strips of 10 tablets each. Each enteric coated tablet contains pantoprazole sodium sesquihydrate USP equivalent to pantoprazole 20 mg.

Panoral® 40 tablet: Box containing 4 strips of 10 tablets each. Each enteric coated tablet contains pantoprazole sodium sesquihydrate USP equivalent to pantoprazole 40 mg.

SK+F

Manufactured by
ESKAYEF BANGLADESH LIMITED
GAZIPUR, BANGLADESH

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