

COMPOSITION

Trupan® 20 Tablet: Each delayed release tablet contains Pantoprazole sodium sesquihydrate INN equivalent to Pantoprazole 20 mg.

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PHARMACOLOGY

Pantoprazole, a substituted benzimidazole, is a proton pump inhibitor. Pantoprazole inhibits secretion of gastric acid by blocking the H⁺ adenosine triphosphatase enzyme system, the final step in acid production in the parietal cell. Absorption of Pantoprazole begins within 30 minutes. Pantoprazole does not accumulate and its pharmacokinetics are suitable for daily dosing. Following oral administration, the plasma concentration of Pantoprazole declines biexponentially with a terminal elimination half-life of approximately 1 hour. Pantoprazole is well absorbed. Administration of Pantoprazole delays gastric absorption up to 2 hours or longer; however, the rate and extent of absorption are not altered. Thus, Pantoprazole should be administered before meals. Pantoprazole is extensively metabolized by the cytochrome P-450 (CYP) system. After a single oral dose, approximately 82% is excreted in the urine with 18% excreted in the feces through the excretion of unchanged Pantoprazole.

INDICATION

Benign gastric ulcer, duodenal ulcer, gastroesophageal reflux disease, and

Pantoprazole is contraindicated in patients with known hypersensitivity to pantoprazole or any other components of the formulation.

PRECAUTION

Patients should be cautioned that this tablet should be swallowed whole, with or without food. The administration of antacids does not affect the

DRUG INTERACTIONS

Pantoprazole is metabolized through the cytochrome P450 CYP2C19 and CYP3A4 isozymes, and subsequent to the inhibition of gastric acid secretion. Based on studies evaluating possible interactions, no dosage adjustment is needed with concomitant administration of pantoprazole with cisapride, antipyrine, caffeine, carbamazepine, desmethyldiazepam), diclofenac, naproxen, progestin oral contraceptive (levonorgestrel/ethinyl estradiol), warfarin (see below), midazolam, clarithromycin. Pantoprazole causes of profound and long lasting inhibition of gastric acid secretion which interfere with absorption of drugs where gastric pH affects bioavailability (eg, ketoconazole, ampicillin esters, and iron

USE IN PREGNANCY AND LACTATION

Teratology studies have been performed in a