COMPOSITION :

Each enteric coated tablet contains:
Pantoprazole Sodium Sesquihydrate IP
Equivalent to Pantoprazole……40 mg.
Excipients……q.s.
Colour : Sunset Yellow FCF.

MECHANISM OF ACTION :

Pantoprazole is converted to its active form in the acidic canaliculi of the parietal cells when it inhibits the H+, K+-AT Pase 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.

PHARMACOLOGY :

PHARMACOKINETICS :

Pantoprazole is rapidly absorbed and the maximal plasma concentration is achieved even after a single oral dose. On average at about 2.0 h - 2.5 h p.a. Volume of distribution is about 0.15 L/kg and clearance is about 0.1 L/h/kg. Terminal half-life is about 1 hour. Pharmacokinetics does not vary after single or repeated administration. In the dose range of 10 to 80mg, the plasma kinetics of Pantoprazole is virtually linear after both oral and intravenous administration.

Pantoprazole serum protein binding is about 98%. The substance is almost exclusively metabolized in the liver. Renal elimination represents the major route of excretion (about 80%) for the metabolites of Pantoprazole, the rest are excreted with the faeces. The main metabolite in both the serum and urine is desmethyl pantoprazole which is conjugated with sulphate. The half-life of the main metabolite (about 1.5 h) is not much longer than that of Pantoprazole. Pantoprazole is completely absorbed after oral administration. The absolute bioavailability from the tablet was found to be about 77%. Only the variability of bioavailability by concomitant food intake.

INDICATIONS :

Gastric ulcer.
Duodenal ulcer.
Peptic ulcers or reflux esophagitis.
Zollinger-Ellison syndrome.

DOSAGE AND ADMINISTRATION :

EROPAN - 40 mg once daily.

WARNINGS & PRECAUTIONS :

Children: The use of Pantoprazole in children has not been studied.
Liver impairment: It is advisable to take one dose of EROPAN 40 mg every two days.
Carcinoid tumors or malignancy should be excluded prior to prescribing EROPAN 40.
Periodic liver function tests should be done during treatment.

PREGNANCY AND LACTATION :

Pregnancy Category B, this drug should be used during pregnancy only if clearly needed. Pantoprazole excretion in human milk has been detected in a study of a single nursing mother after a single 40 mg oral dose. The clinical relevance of this finding is not known, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

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SIDE EFFECTS :

EROPAN 40 is well tolerated, only few cases of headache, diarrhoea, dizziness, skin rashes and pruritus have been reported.

CONTRAINDICATIONS :

Pantoprazole contraindicated with hypersensitivity to salt. Pantoprazole, like other proton pump inhibitors, should not be co-administered with atazanavir.

DRUG INTERACTIONS :

It may reduce or increase the absorption of drugs whose bioavailability is pH-dependent (e.g. ketoconazole).

OVERDOSAGE :

Adosage of 240 mg. of Pantoprazole has been well tolerated.
Apart from symptomatic treatment, no specific therapeutic recommendation can be made in cases of overdosage.
Pantoprazole is slightly removed from the circulation by hemodialysis.

PACKAGING INFORMATION :

EROPAN 40 : Available in a strip of 10 tablets.