EIREF-C

Pantoprazole 40 mg and Cinitapride 3 mg SR Capsules





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INTRODUCTION:

Gastroesophageal Reflux Disease (GERD) and Functional Dyspepsia (FD) are the two most prevalent upper gastrointestinal disorders. A number of pathophysiological factors are common to GERD and functional dyspepsia. The prevalence of GERD in India ranges from 7.6% to 30%.

CLINICAL EVIDENCE:

1 EFFICACY AND SAFETY OF CINITAPRIDE IN FUNCTIONAL DYSPEPSIA

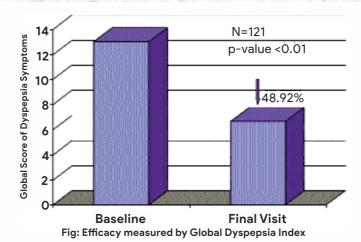
Vol. 63, No. 6, June 2013

No. of Patients: 121 (Patients > 18 years of age)

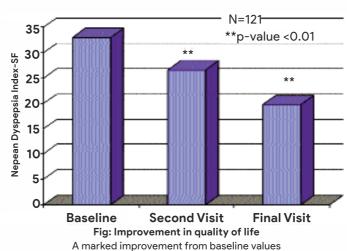
Duration: 4 Weeks

Dose: Cinitapride 1 mg thrice daily 15 minutes before meal

Result:



Baseline Global Dyspepsia Index (GDI) was 13.02±6.31. At the end of four weeks the GDI came down to 6.65±4.05 (p<0.0001).



32.98±8.36 to 26.61±6.65 (p<0.01) at week 2 and at week 4 and further improved to 19.81+5.82 (p<0.01).

CONCLUSION:

Cinitapride is effective in minimising dyspepsia symptoms, and improving the quality of life of patients. It is well tolerated and almost free of side effects.

2 ORAL PANTOPRAZOLE FOR EROSIVE ESOPHAGITIS

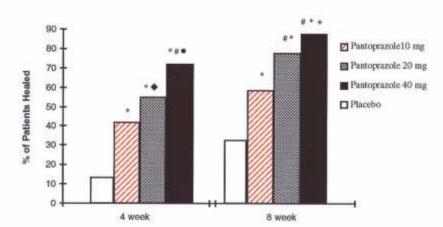
AJG - Vol. 95, No. 11, 2000

No. of Patients: 603 patients (Patients≥18 years of age)

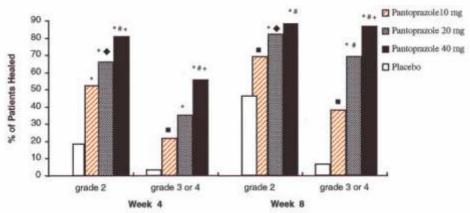
Duration: 8 Weeks

Dose: Pantoprazole (10 mg, 20 mg, or 40 mg) or placebo, OD in the morning.

Result:



Endoscopic healing rates: percentage (%) of patients healed after 4 and 8 week according to treatment regimen.



Percentage (%) of patients healed according to initial disease severity.

Endoscopic healing rates shown by treatment regimen after 4 and 8 weeks of treatment.

CONCLUSION:

The pantoprazole 40 mg produces a significantly greater healing rate than either 10 or 20 mg of pantoprazole ($p \le 0.001$ vs pantoprazole 10 mg and 20 mg).

CINITAPRIDE IN EIREF-C:

- Cinitapride is a gastroprokinetic/gastrointestinal promotility drug and antiulcer agent of the benzamide class.
- lt is metabolized by both cytochrome P450 (CYP) 3A4 enzyme and CYP2C8, Because of that the risk of drug interaction is lower.³
- The free drug concentration of cinitapride is much lower than that of cisapride and domperidone, resulting in a lower risk of cardiotoxicity.3

PANTOPRAZOLE IN EIREF-C:

- Pantoprazole, a substituted benzimidazole, inhibits the final step of gastric acid production. 4
- Pantoprazole exhibits the lowest acid activation at less acidic pH.⁴
- 6 It is approved by the FDA for the treatment of erosive esophagitis associated with GERD.



Pantoprazole 40 mg and Cinitapride 3 mg SR Capsules

DESCRIPTION:

EIREF-C contains Cinitapride in combination with Pantoprazole in the strength of 3 mg + 40 mg and available as hard gelatin capsule.

INDICATIONS:

In the treatment of patients suffering from Non-Ulcer Dyspepsia (NUD) or Gastroesophageal Reflux Disease (GERD).

MECHANISMOFACTION:

CINITAPRIDE:

Cinitapride is a gastroprokinetic and antiulcer benzamide with agonist activity at 5-HT1 and 5-HT4 receptors and antagonist
activity at 5-HT2 receptors. It blocks the presynaptic serotonin receptors and increases its release, resulting in greater
serotonergic activity.

PANTOPRAZOLE:

- Pantoprazole is a substituted benzimidazole which inhibits the secretion of hydrochloric acid in the stomach by specific blockade of the proton pumps of the parietal cells.
- Pantoprazole is converted to its active form in the acidic environment in the parietal cells where it inhibits the H+K+-ATPase enzyme, i. e. the final stage in the production of hydrochloric acid in the stomach.

DOSAGEANDADMINISTRATION:

- The recommended dose is 1 capsule once daily or as directed by the Physician.
- Method of administration: For oral administration only. The capsules should not be chewed or crushed, and should be swallowed whole 1 hour before a meal with some water.

STORAGE:

Store protected from light and moisture at a temperature not exceeding 30°C

PRESENTATION:

EIREF-C is available as 10 capsules in a strip.

Reference:

1. Nat. Rev. Gastroenterol. Hepatol. 10, 175–186 (2013) 2. Indian Society of Gastroenterology 2019 3. ADRJ, February 2019, Vol 21 . No. 1 4. AJG – Vol. 95, No. 11, 2000



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