St. John's Wort, rifampin: Avoid concomitant use with lansoprazole.

• The tablet typically disintegrates in less than one minute.

• Take two doses at one time to make up for a missed dose.

• Dual Therapy: Lansoprazole delayed-release orally disintegrating tablets are indicated in adults to maintain healing and symptom relief of active duodenal ulcer for four weeks) for healing and symptom relief of active duodenal ulcer [see Clinical Studies (14.6)]

• Indication Recommended Dose Frequency

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance of Healed</td>
<td>15 mg</td>
<td>Once daily</td>
</tr>
<tr>
<td>Dual Therapy:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Lansoprazole delayed-release orally disintegrating tablets contain phenylalanine, a component of aspartame. Each 15 mg tablet contains

• Cyanocobalamin (Vitamin B12) Deficiency: Lansoprazole delayed-release orally disintegrating tablets are indicated in adults to maintain healing and symptom relief of active duodenal ulcer for four weeks) for healing and symptom relief of active duodenal ulcer [see Clinical Studies (14.6)]

• Contraindicated in patients with known

• Treatment of erosive esophagitis (EE) in adults and

• Impairment of Fertility

• Other Gastric Effects in Humans

• Rule out the possibility of an increased risk of the development of gastric tumors in patients receiving

• Enterochromaffin-like (ECL) Cell Effects

• Potential for increased exposure of digoxin.

• Intervention: Lansoprazole delayed-release orally disintegrating tablets contain phenylalanine, a component of aspartame. Each 15 mg tablet contains

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• Intervention:
Male and Female Patients:

**Elimination**

Evidences of a change in the efficacy of lansoprazole.

**Antacids:**

In a single-dose crossover study examining lansoprazole 30 mg administered alone and 72 mg of seven days of naproxen 500 mg twice daily and lansoprazole 30 mg daily had no effect on the plasma elimination half-life of lansoprazole. However, the inter-individual variability was high. The Cmax values were comparable.

**Theophylline:**

Lansoprazole is metabolized through the cytochrome P450 system, specifically through the CYP3A4 enzyme. Lansoprazole does not appear to have a clinically significant effect on theophylline metabolism, with the exception of patients with liver disease.

**Reproductive Toxicology Studies:**

Lansoprazole is 97% bound to plasma proteins. Plasma protein binding is constant over the dose range studied. Although the volume of distribution of lansoprazole approximates the volume of the plasma compartment, significant amounts of lansoprazole are not present in the systemic circulation. The plasma elimination half-life of lansoprazole is less than 1 hour.

**Effect on Sexual Function:**

In addition, lansoprazole in oral doses of 15 to 60 mg for two to eight weeks had no effect on sexual function. There was no evidence of a greater or earlier response with the two regimens compared to placebo.

**Abdominal Pain and Antacid Use:**

In a 12-week, placebo-controlled trial, lansoprazole 15 mg and 30 mg per day were studied. Lansoprazole was superior to placebo in reducing the mean number of abdominal pain episodes per week (91.7% vs 81.4%). In a separate study, lansoprazole was compared to ranitidine 150 mg twice daily in decreasing the frequency and severity of day and nighttime heartburn associated with GERD. Lansoprazole 30 mg once daily was observed to be significantly more effective than ranitidine 150 mg twice daily in decreasing the frequency and severity of day and nighttime heartburn.

**Placebo-Controlled Studies:**

- **Double-Blind, Multi-Center, Controlled Trials:**
  - Two independent, double-blind, multi-center, controlled trials were conducted in patients with endoscopically documented duodenal ulcer disease. Lansoprazole 15 mg and 30 mg per day for four weeks were compared to placebo.

**Endoscopic Healing Rates**

- **Table 10.**
  - Lansoprazole 30 mg per day was significantly more effective than placebo in achieving endoscopic healing of duodenal ulcer at four weeks. The healing rates were 93% for Lansoprazole 30 mg, 83% for Lansoprazole 15 mg, and 49% for placebo. The difference between Lansoprazole 30 mg and placebo was statistically significant (p < 0.05).

**H. pylori Detection:**

- **CLOtest, Histology and/or Culture:**
  - Patients were included in the analysis if they completed the study. The prevalence of H. pylori infection was determined by CLOtest, histology, and/or culture. Patients treated with lansoprazole remained asymptomatic for a significantly longer period of time after eradication of H. pylori compared to patients treated with lansoprazole alone or placebo.

**Adverse Events:**

- **Associated Diarrhea:**
  - There were no differences in the rates of any adverse event between patients treated with lansoprazole and patients treated with placebo. The median duration of diarrhea was longer in patients treated with lansoprazole than in patients treated with placebo.

**Warnings and Precautions:**

- **Hypomagnesemia:**
  - Magnesium levels should be monitored in patients treated with lansoprazole, particularly those with pre-existing hypomagnesemia.

**Use of Other Medications:**

- **Corticosteroids, Cyclosporine, and Fluoroquinolones:**
  - Lansoprazole is metabolized through the cytochrome P450 system, specifically through the CYP3A4 enzyme. Lansoprazole does not appear to have a clinically significant effect on theophylline metabolism, with the exception of patients with liver disease.

**Antacids:**

- **Effect on theophylline metabolism:**
  - Lansoprazole does not appear to have a clinically significant effect on theophylline metabolism, with the exception of patients with liver disease.

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