Helicobacter pylori

Initial U.S. Approval: 1999

RABEPRAZOLE sodium delayed-release tablets.

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and nighttime heartburn scores were significantly greater for rabeprazole 20 mg as compared to those with daytime and nighttime heartburn. Patients reported 5 or more periods of moderate heartburn.

### DAYTIME AND NIGHTTIME HEARTBURN SEVERITY AT WEEK 52

<table>
<thead>
<tr>
<th>Study 1</th>
<th>N = 66</th>
<th>N = 67</th>
<th>N = 70</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nighttime Heartburn Severity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 26</td>
<td>82%a</td>
<td>91%a</td>
<td>31%</td>
</tr>
<tr>
<td>Week 52</td>
<td>73%a</td>
<td>90%a</td>
<td>29%</td>
</tr>
<tr>
<td>Week 39</td>
<td>76%a</td>
<td>91%a</td>
<td>30%</td>
</tr>
</tbody>
</table>

**Study 2**: 73/84 (87%)b 82/87 (94%)a 67/90 (74%)c

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### 14.5 Rabeprazole 20 mg also significantly reduced daily antacid consumption versus placebo

Rabeprazole 20 mg significantly improved other GERD-associated symptoms (regurgitation, belching and early emptiness feel of stomach). In addition, the combined analysis of these two studies showed rabeprazole 20 mg significantly improved other GERD-related symptoms (regurgitation, belching, and early emptiness feel of stomach) compared to placebo.

**Table 11: Healing of Duodenal Ulcers Percentage of Patients Healed**

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Percent (%) of Patients Healed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intent-to-Treat</td>
<td>78.1% (N = 196) 73.3% (N = 206) 4.8 [-3.6, 13.2]</td>
</tr>
<tr>
<td>Per Protocol</td>
<td>84.3% (N = 166) 81.6% (N = 179) 2.8 [-5.2, 10.7]</td>
</tr>
</tbody>
</table>

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### 14.7 Pediatric GERD

Pediatric regimens were used in 10 pediatric patients with peptic disease in all patients. The high doses of rabeprazole used to treat this small cohort were only used in the pediatric patients. Additional information about pediatric use is found in Section 16.10.2.4b.

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### 1.3.3 National Committee for Clinical Laboratory Standards.

1. National Committee for Clinical Laboratory Standards.

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### 10. Details about rabeprazole sodium delayed-release tablets

**TEVA PHARMACEUTICAL IND. LTD.**

**TEVA PHARMACEUTICALS USA**

Manufactured For: TEVA PHARMACEUTICALS USA

Manufactured In Israel By: TEVA PHARMACEUTICAL IND. LTD.

Manufactured For: TEVA PHARMACEUTICALS USA

Seltzer, PA 19860

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