History of hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the strains of Escherichia coli.

In the absence of such data, local epidemiology and susceptibility patterns may available, they should be considered in selecting or modifying antibacterial therapy.

To reduce the development of drug-resistant bacteria and maintain the effectiveness XIFAXAN® (rifaximin) tablets, for oral use.

HIGHLIGHTS OF PRESCRIBING INFORMATION

Limitations of Use

XIFAXAN is a rifamycin antibacterial indicated for:

- Initial U.S. Approval: 2004

2.2 Dosage for Hepatic Encephalopathy

- Hepatic Encephalopathy

5.3 Development of Drug-Resistant Bacteria

14.2 Hepatic Encephalopathy

5.1 Travelers’ Diarrhea Not Caused by

15 REFERENCES

- Travelers’ Diarrhea

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

13.2 Reproduction

- Groups and age subpopulations.

Table 1: Mean Plasma Concentrations of Rifaximin in Patients with Renal Impairment

<table>
<thead>
<tr>
<th>Condition</th>
<th>Plasma Concentration</th>
<th>AUC0-last (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>25 (20)</td>
<td>96.2</td>
</tr>
<tr>
<td>Renal Impairment</td>
<td>25 (20)</td>
<td>96.2</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>25 (20)</td>
<td>96.2</td>
</tr>
</tbody>
</table>

- Patients with severe hepatic impairment, including patients with severe Child-Pugh Class C cirrhosis.

- There were no significant differences in plasma concentration-time profiles between patients with severe hepatic impairment and healthy patients.

Table 2: Mean Plasma Concentrations of Rifaximin in Patients with Hepatic Encephalopathy

<table>
<thead>
<tr>
<th>Condition</th>
<th>Plasma Concentration</th>
<th>AUC0-last (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>25 (20)</td>
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</tr>
<tr>
<td>Cirrhosis</td>
<td>25 (20)</td>
<td>96.2</td>
</tr>
<tr>
<td>HE</td>
<td>25 (20)</td>
<td>96.2</td>
</tr>
</tbody>
</table>

- There were no significant differences in plasma concentration-time profiles between patients with HE and healthy patients.

Table 3: Mean Plasma Concentrations of Rifaximin in Patients with Hepatic Encephalopathy

<table>
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Table 4: Mean Plasma Concentrations of Rifaximin in Patients with Hepatic Encephalopathy

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<td>96.2</td>
</tr>
</tbody>
</table>

- There were no significant differences in plasma concentration-time profiles between patients with HE and healthy patients.

Table 5: Mean Plasma Concentrations of Rifaximin in Patients with Hepatic Encephalopathy

<table>
<thead>
<tr>
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Table 6: Mean Plasma Concentrations of Rifaximin in Patients with Hepatic Encephalopathy

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<tr>
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<td>25 (20)</td>
<td>96.2</td>
</tr>
</tbody>
</table>

- There were no significant differences in plasma concentration-time profiles between patients with HE and healthy patients.
Drug Resistance and Cross-Resistance

12.4 Microbiology

Standards Institute (CLSI). However, the correlation between susceptibility testing
in clinical studies of infectious diarrhea as described in the

Rifaximin was not genotoxic in the bacterial reverse mutation assay, chromosomal
function and an increase of Conn score to Grade ≥2. In patients with a baseline Conn
score ≥1, the percentage of patients who developed Grade ≥2 abnormalities on XIFAXAN
was significantly lower compared with placebo (p < 0.05).

In an open-label, 8-week study, 86 patients with a baseline Conn score of ≥1 were
randomized into the double-blind, placebo-controlled repeat treatment phase. Of
these patients, 63 (73%) were randomized to receive placebo and 23 (27%) were
randomized to receive 550 mg XIFAXAN 2 times a day. The efficacy of XIFAXAN 550 mg
5.1 Pharmacokinetics

The mean half-life of XIFAXAN 550 mg was 10 hours in healthy subjects. In healthy
subjects, the clearance of XIFAXAN 550 mg is approximately 44% lower after the
7-day XIFAXAN regimen compared to the single-dose regimen. The volume of
distribution is approximately 180 L and is not affected by the dose administered or
administered as a single dose or divided into 2 doses over 12 hours.

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