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DESCRIPTION
Letrozole tablets USP for oral administration contain 2.5 mg of Letrozole, a nonsteroidal aromatase inhibitor. Letrozole is described as 4,4'-[(4H-1,3,4-Benzotriazin-3-yl)methylene]bis(3-oxopropyl) and its structural formula is.

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TROZET 2.5 mg/5 ml Antineoplastic

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Table 15: Percentage (%) of patients with Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Letrozole (N=455)</th>
<th>Placebo (N=257)</th>
<th>N=2563</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>526 (11.6%)</td>
<td>363 (14.0%)</td>
<td>4.8%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1298 (28.8%)</td>
<td>1298 (28.8%)</td>
<td>28.4%</td>
</tr>
<tr>
<td>Back pain</td>
<td>1033 (22.8%)</td>
<td>1033 (22.8%)</td>
<td>17.7%</td>
</tr>
<tr>
<td>Nausea</td>
<td>552 (11.8%)</td>
<td>552 (11.8%)</td>
<td>11.6%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>457 (9.9%)</td>
<td>457 (9.9%)</td>
<td>8.3%</td>
</tr>
<tr>
<td>Skin Disorders</td>
<td>552 (11.8%)</td>
<td>552 (11.8%)</td>
<td>11.6%</td>
</tr>
<tr>
<td>Infections and Infestations</td>
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</tr>
</tbody>
</table>

The duration of follow-up for both the main clinical study and the bone study was insufficient to assess fracture risk associated with long-term use of Letrozole. Based on a median follow-up of patients for 26 months, the incidence of clinical fractures from the core randomized study in patients who received Letrozole was 0.5% (152) and placebo was 0.5% (142). The incidence of self-reported osteoporotic fractures in patients who received Letrozole was 0.7% (17) and in patients who received placebo 0.5% (14). Bisphosphonates were administered to 21.1% of the patients who received Letrozole and 16.7% of the patients who received placebo.

Other less frequent (0.2%) adverse experiences considered relevant for both treatment groups included peripheral thromboembolic events, cardiovascular events, and cerebrovascular events. Peripheral thromboembolic events included venous thrombosis, thrombophlebitis, portal vein thrombosis and pulmonary embolism. Cardiovascular events included angina, myocardial infarction, myocardial ischemia, and coronary heart disease. Cerebrovascular events included transient ischemic attacks, thrombosis or hemorrhagic stroke and development of hemiparesis.

Second-Line Breast Cancer

Letrozole was generally well tolerated in two controlled clinical trials. Study discontinuations in the breast cancer comparison study for adverse events other than progression of tumor occurred in 496 patients on Letrozole 2.5 mg, and in 496 patients on placebo. Adverse reactions due to treatment from both letrozole and placebo were mild to moderate in severity and it was generally not possible to distinguish adverse reactions due to treatment from the consequences of the patient’s metastatic breast disease. None of these adverse events were of sufficient severity to require withdrawal from the study.

Comparisons of the incidence of adverse events revealed no significant differences between the high and low dose Letrozole groups in either study. Most of the adverse events observed in all clinical trials were mild to moderate in severity and it was generally not possible to distinguish adverse events due to treatment from the consequences of the patients’ metastatic breast cancer. The effects of osteoporosis, depression, or intercurrent illnesses.}

First-Line Breast Cancer

A total of 456 patients were treated for a median time of exposure of 11 months. The incidence of adverse experiences assessed in this analysis was similar to that reported in the high-dose group. The proportions of patients with adverse experiences were similar in both groups and no statistically significant differences were detected.

A patient-reported measure that captures treatment impact on important symptoms associated with osteoporoid dependency demonstrated a difference in favor of placebo for vasoactive and sexual symptoms.

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