**ADVERSE REACTIONS**

These adverse reactions were observed in clinical trials of bicalutamide in combination with an LHRH analog. The most frequent reactions associated with bicalutamide 50 mg daily were gynecomastia (12%), abdominal pain (7%), headache (7%), peripheral edema (5%), and fatigue (4%). In patients treated with bicalutamide 150 mg daily, the most frequent reactions associated with bicalutamide were gynecomastia (8%), abdominal pain (4%), fatigue (3%), headache (2%), and peripheral edema (2%).

**WARNINGS AND PRECAUTIONS**

5.3 Pregnancy

- Bicalutamide is contraindicated in women. Bicalutamide has no indication for women, and should not be used in this population.

5.4 Adverse Reactions

- In patients with advanced prostate cancer treated with bicalutamide plus an LHRH analog, the most frequent adverse reactions were hyperglycemia, proteinuria, and gynecomastia.

**DRUG INTERACTIONS**

- Bicalutamide is an inhibitor of CYP 3A4; therefore, caution should be used when bicalutamide is co-administered with CYP 3A4 substrates.

**DOSAGE AND ADMINISTRATION**

- Bicalutamide is available as tablets containing 50 mg or 150 mg of the active ingredient (r-bicalutamide) as indicated in the table below:

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Number of Tablets</th>
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<tbody>
<tr>
<td>50 mg</td>
<td>100</td>
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<tr>
<td>150 mg</td>
<td>50</td>
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</tbody>
</table>

- Bicalutamide 50 mg daily is indicated for use alone or with other treatments.

**INDICATIONS AND USAGE**

- Bicalutamide 50 mg daily is indicated for use alone or with other treatments.

**WARNINGS AND PRECAUTIONS**

- Bicalutamide 150 mg daily is not approved for use alone.

**CONTRAINDICATIONS**

- Bicalutamide is contraindicated in women.

**ADVERSE REACTIONS**

- Adverse reactions that occurred in more than 10% of patients receiving bicalutamide plus an LHRH-A were: hot flashes (52%), fatigue (26%), abdominal discomfort (19%), peripheral edema (12%), dyspepsia (12%), diarrhea (12%), hematuria, nocturia, and anemia (6%).

- Adverse reactions that occurred in more than 5% of patients receiving bicalutamide plus an LHRH-A were: hot flashes (52%), fatigue (26%), abdominal discomfort (19%), peripheral edema (12%), dyspepsia (12%), diarrhea (12%), hematuria, nocturia, and anemia (6%).

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nonclinical toxicity. There is no evidence that bisphenol A has been shown to be carcinogenic in any animal studies. There is no evidence indicating that bisphenol A is mutagenic or that it has been shown to be embryotoxic or teratogenic in animal studies. There is no evidence indicating that bisphenol A is genotoxic. There is no evidence indicating that bisphenol A is teratogenic or that it has been shown to be embryotoxic or teratogenic in animal studies. There is no evidence indicating that bisphenol A is mutagenic. There is no evidence indicating that bisphenol A is carcinogenic.

1.5. Rare Events in Clinical Studies

1.6. Pharmacokinetics

1.7. Metabolism

1.8. Excretion

1.9. Special Populations

1.10. Undesirable Effects

1.11. Overdosage

1.12. Nursing Mothers

1.13. PREGNANCY

1.14. Breastfeeding

1.15. GERIATRIC USE

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