Bicalutamide Tablets

**INDICATIONS AND USAGE**

Bicalutamide Tablets are a prescription medicine called an androgen receptor inhibitor, used in combination with a luteinizing hormone-releasing hormone (LHRH) medication to treat stage D2 metastatic prostate cancer.

**CONTRAINDICATIONS**

- Bicalutamide Tablets are contraindicated in a patient who has a known or suspected active tumor, in the event of an acute myocardial infarction (MI) or drug-related hepatic injury.

**WARNINGS AND PRECAUTIONS**

- Bicalutamide Tablets are used in combination with a LHRH agent. LHRH agents have been shown to reduce testosterone levels to castrate levels in men. Bicalutamide has also been shown to reduce testosterone levels in patients who are inherently hypogonadal (i.e., men with pre-existing testosterone levels in the castrate range).

**ADVERSE REACTIONS**

- The most common adverse reactions are headaches, back pain, and urinary symptoms.

**DRUG INTERACTIONS**

- Bicalutamide may increase the effect of other medicines that thin your blood. Ask your healthcare provider or pharmacist if you are not sure if your medicine is a blood thinner.

**DOSAGE AND ADMINISTRATION**

- Bicalutamide Tablets should be taken at the same time each day. Treatment with Bicalutamide Tablets should be started at the same time you start taking it and each time you get a refill.

**DOSE AND RESPONSE**

- No dose adjustment is necessary for patients with renal impairment.

**DOSE FORMS AND STRENGTHS**

- 50 mg tablets

**INFORMATION FOR PATIENTS**

- This leaflet does not take the place of talking with your healthcare provider about your medical condition.

**ADDITIONAL INFORMATION**

- This is not all the information that is known about bicalutamide and bicalutamide tablets.

**PHARMACOKINETICS**

- Bicalutamide tablets are well absorbed and distributed throughout the body. The absolute bioavailability of bicalutamide is approximately 50%.

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**ADDITIONAL INFORMATION**

- This is not all the information that is known about bicalutamide and bicalutamide tablets.
An allergic reaction of the sensitivity reaction includes itching, swelling of the eyes, nose, lips, tongue or throat, difficulty swallowing.

- yellowing of the skin and eyes (jaundice), dark urine, right upper stomach pain, nausea, vomiting, tiredness, loss of appetite, chills, fever, whole body pain. These may be symptoms of liver injury.
- Poor blood sugar control can happen in people who take Bicalutamide Tablets in combination with LH-RH medications.

The most common side effects of Bicalutamide Tablets include:
- hot flashes, or short periods of feeling warm and sweating
- whole body pain in your back, penis, stomach
- feeling weak
- constipation
- fever
- nausea
- swelling in your ankles, legs or feet
- diarrhea in your blood
- waking from sleep to urinate at night
- a decrease in red blood cells (anemia)
- feeling dizzy

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Bicalutamide Tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

10. OVERDOSAGE

- Symptoms of an overdose include:
  - vomiting
  - increased heart rate
  - shallow breathing
  - dizziness
  - convulsions
  - coma

- Call your doctor or go to the nearest hospital if you think you have taken too much Bicalutamide Tablets. The amount of medicine taken at one time or the number of times the medicine is taken also affects the amount of poisoning. The amount of medicine that causes poisoning or death also varies from person to person.

11. DESCRIPTION

11.1. Chemical Name and CAS Registry Numbers

- Bicalutamide Tablets contain 50 mg of bicalutamide, a non-steroidal androgen in adults with hormone-refractory prostate cancer. Bicalutamide is a white or almost white powder which is practically odorless in water and soluble in ethanol.

- The structural formula of is as follows:

11.2. Empirical Formula and Molecular Weight

- Bicalutamide is a non-steroidal androgen receptor inhibitor. It competitively inhibits the action of androgens by binding to the androgen receptor and prevents androgen receptor mRNA translation which reduces the amount of androgens.

11.3. Physical and Chemical Properties

- Bicalutamide is a white or almost white powder which is practically odorless in water and soluble in ethanol. It is stable to hydrolysis by enzymes and is not significantly affected by light exposure. Bicalutamide is stable in the presence of the following:

11.4. Stability Information

11.5. Pharmacokinetics

11.6. Absorption

11.7. Distribution

11.8. Metabolism

11.9. Excretion

11.10. Overdosage

11.11. Information for Patients

11.12. Animal Data

11.13. Human Data

11.14. Preclinical Pharmacology

11.15. Preclinical Toxicology

12. CLINICAL PHARMACOLOGY

12.1. Pharmacokinetics

12.2. Pharmacodynamics

12.3. Effect on Laboratory Tests

12.4. Special Populations

13. ADVERSE REACTIONS

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13.2. Clinical Trials

13.3. Post-Marketing Surveillance

14. INDICATIONS AND USAGE

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14.2. Post-Marketing Experience

14.3. Use in Children and Adolescents

14.4. Use in Renal Impairment

14.5. Use in Hepatic Impairment

14.6. Use in Other Special Populations

15. DRUG INTERACTIONS

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15.2. Benzodiazepines

15.3. Oral Contraceptives

15.4. pylori Infections

15.5. Strong CYP3A4 Inhibitors

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16.2. Nursing Mothers

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16.4. Pediatric Use

16.5. Hypersensitivity Reactions

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17.3. Low Density Lipoprotein Cholesterol (LDL-C)

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19.6. Bicalutamide plus hormone therapy

19.7. Bicalutamide plus chemotherapy

19.8. Bicalutamide plus hormone therapy

19.9. Bicalutamide plus chemotherapy

19.10. Bicalutamide plus hormone therapy

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21.2. How to take

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26.5. Disposal

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27. PATIENTS' MEDICATION GUIDE

27.1. General Information

27.2. How to take

27.3. Missed Dose

27.4. Store

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27.6. Other information
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/s/

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