

PATIENT INFORMATION

Bicalutamide Tablets

[bye-kah-LEW-tuh-mide]

What are bicalutamide tablets?

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

Bicalutamide tablets 150 mg daily is not approved for use alone or with other treatments.

It is not known if bicalutamide tablets are safe and effective in children.

Do not take bicalutamide tablets if you are:

- allergic to bicalutamide or any of the ingredients in bicalutamide tablets. See the end of this Patient Information leaflet for a complete list of ingredients in bicalutamide tablets. Get medical help right away if you develop any of the following symptoms of an allergic reaction:
 - itching
 - swelling of the face, lips or tongue
 - hives (raised bumps)
 - trouble breathing or swallowing
- female. Bicalutamide tablets is not for use by women
- pregnant or may become pregnant. Bicalutamide tablets may harm your unborn baby.

Before taking bicalutamide tablets, tell your healthcare provider about all your medical conditions, including if you:

- have liver problems.
- take a medicine to thin your blood. Ask your healthcare provider or pharmacist if you are not sure if your medicine is a blood thinner.
- have diabetes.
- have a female partner who can become pregnant. Males who have a female partner who can become pregnant should use effective birth control during treatment with bicalutamide tablets and for 130 days after the final dose. Talk to your healthcare provider if you have any questions about birth control.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Bicalutamide tablets may affect the way other medicines work and other medicines may affect how bicalutamide tablets works, causing side effects.

Know the medicines you take. Keep a list of your medicines with you to show your healthcare providers when you get a new medicine.

How should I take bicalutamide tablets?

- Take bicalutamide tablets exactly as your healthcare provider tells you to take it.
- Do not stop taking bicalutamide tablets unless your healthcare provider tells you to.
- Bicalutamide tablets can be taken either in the morning or in the evening, but you should take it at the same time every day.
- Your treatment with bicalutamide tablets should start at the same time as your treatment with the LHRH medicine.
- If you miss a bicalutamide tablets dose do not take the missed dose, take the next dose at your next scheduled time. Do not take 2 doses at the same time.
- Bicalutamide tablets can be taken with or without food.
- If you take too much bicalutamide tablets, call your healthcare provider or go to the nearest hospital emergency room right away

What should I avoid during treatment with bicalutamide tablets?

- Do not drive, operate machinery, or do other dangerous activities until you know how bicalutamide tablets affect you. Bicalutamide tablets can make you sleepy.
- Avoid sunlight, sunlamps and tanning beds and consider using sunscreen during treatment with bicalutamide tablets. Some people have had skin sensitivity to sunlight during treatment with bicalutamide tablets.

What are the possible side effects of bicalutamide tablets?

Bicalutamide may cause serious side effects, including.

- **Liver problems.** Severe liver problems including liver failure that may need to be treated in a hospital or that may lead to death have happened in people who take bicalutamide tablets Your healthcare provider should do blood tests to check your liver function before and during treatment with bicalutamide tablets. Tell your healthcare provider right away if you develop any of these symptoms of liver problems during treatment:
 - yellowing of the skin and eyes (jaundice)
 - dark urine
 - right upper stomach pain
 - nausea
 - vomiting
 - tiredness

- loss of appetite
- chills
- fever

- **Bleeding problems.** Serious bleeding problems have happened in people who take bicalutamide tablets in combination with a blood thinner medicine (coumarin anticoagulants). Bleeding problems have happened days to weeks after starting bicalutamide tablets treatment. If you take a blood thinner medicine during treatment with bicalutamide tablets, tell your healthcare provider if you develop any bleeding or unexplained bruising.

- **Breast enlargement (gynecomastia) and breast pain.**

- **Blood sugar problems.** Poor blood sugar control can happen in people who take bicalutamide tablets in combination with LHRH medicines.

Your healthcare provider may do blood tests during treatment with bicalutamide tablets to check for side effects.

Your prostate cancer may get worse during treatment with bicalutamide tablets in combination with LHRH medicines. Regular monitoring of your prostate cancer with your healthcare provider is important to determine if your disease is worse.

Tell your healthcare provider if you have trouble breathing with or without a cough or fever. Some people taking bicalutamide tablets get an inflammation in the lungs called interstitial lung disease.

The most common side effects of bicalutamide tablets include:

- hot flashes (short periods of feeling warm and sweating)

- body pain (including back, pelvis, stomach)

- feeling weak

- constipation

- infection

- nausea

- swelling in your arms, ankles, legs or feet
- shortness of breath (dyspnea)
- dizziness
- diarrhea
- blood in your urine
- frequent urination at night
- a decrease in red blood cells (anemia)

Bicalutamide tablets may have an effect on male fertility which could be reversible. Talk to your healthcare provider if this is a concern for you.

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.

How should I store bicalutamide tablets?

Store bicalutamide tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep bicalutamide tablets and all medicines out of the reach of children.

General information about the safe and effective use of bicalutamide tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use bicalutamide tablets for a condition for which it was not prescribed. Do not give bicalutamide tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about bicalutamide tablets. If you would like more information about bicalutamide tablets, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about bicalutamide tablets that is written for health professionals.

For more information, go to www.accordhealthcare.us or call Accord Healthcare at 1-866-941-7875.

What are the ingredients in bicalutamide tablets?

Active ingredient: bicalutamide.

Inactive ingredients: lactose monohydrate, magnesium stearate, hypromellose E5, polyethylene glycol 400, povidone K 30, sodium starch glycolate, and titanium dioxide.

Manufactured For:

Accord Healthcare, Inc.,
1009, Slater Road,
Suite 210-B,
Durham, NC 27703,
USA.

Manufactured By:

Intas Pharmaceuticals Limited,
Plot No. : 457, 458,
Village – Matoda,
Bavla Road, Ta.- Sanand,
Dist.- Ahmedabad – 382 210.
India.

10 0857 3 691691

Issued January 2019