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

The most common side effects of bicalutamide tablets include:

- hot flashes, or short periods of feeling warm and sweating
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- feeling weak
- constipation
- infection
- nausea
- swelling in your ankles, legs or feet
- diarrhea
- blood in your urine
- 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.

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**How should I store bicalutamide tablets?**

Store bicalutamide tablets at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

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

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**What are the ingredients in bicalutamide tablets?**

Active ingredients include: bicalutamide

Inactive ingredients include: colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, polydextrose, polyethylene glycol, povidone, sodium lauryl sulfate, sodium starch glycolate, titanium dioxide and triacetin.

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due to progressive advanced prostate cancer, a reduction in Prostate Specific Antigen (PSA) and/or clinical improvement (antitandrogen withdrawal phenomenon) may be observed.

### 12.3 Pharmacokinetics

Bicalutamide is well-absorbed following oral administration, although the absolute bioavailability is unknown. Coadministration of bicalutamide with food has no clinically significant effect on rate or extent of absorption.

#### Distribution:

Bicalutamide is highly protein bound (96%). [See Drug Interactions (7)].

#### Metabolism/Excretion:

Bicalutamide undergoes stereospecific metabolism. The S (inactive) isomer is metabolized primarily by glucuronidation. The R (active) isomer also undergoes glucuronidation, but is predominantly oxidized to an inactive metabolite followed by glucuronidation. Both the parent and metabolite glucuronides are eliminated in the urine and feces. The S-enantiomer is rapidly cleared relative to the R-enantiomer, with the R-enantiomer accounting for about 99% of total steady-state plasma levels.

Pharmacokinetics of the active enantiomer of bicalutamide tablets in normal males and patients with prostate cancer are presented in Table 2.

#### Table 2

Parameter	Mean	Standard Deviation
<b>Normal Males (n = 30)</b>		
Apparent Oral Clearance (L/hr)	0.320	0.103
Single Dose Peak Concentration (mg/mL)	0.768	0.178
Single Dose Time to Peak Concentration (hours)	3.13	14.6
Half-life (days)	5.8	2.29
<b>Patients with Prostate Cancer (n = 40)</b>		
C <sub>50</sub> (mg/mL)	8.939	3.504

### 13 NONCLINICAL TOXICOLOGY

#### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Two-year oral carcinogenicity studies were conducted in both male and female rats and mice at doses of 5, 15 or 75 mg/kg/day of bicalutamide. A variety of tumor target organ effects were identified and were attributed to the androgenicity of bicalutamide, namely, testicular benign interstitial (Leydig) cell tumors in male rats at all dose levels (the steady-state plasma concentration with the 5 mg/kg/day dose is approximately 2/3 human therapeutic concentrations) and pituitary adenomas in female rats at 75 mg/kg/day (approximately 1/2 times the human therapeutic concentrations). There is no evidence of Leydig cell hyperplasia in patients; uterine tumors are not relevant to the indicated patient population.

A small increase in the incidence of hepatocellular carcinoma in male mice given 75 mg/kg/day of bicalutamide (approximately 4 times human therapeutic concentrations) and an increased incidence of benign thyroid follicular cell adenomas in rats given 5 mg/kg/day (approximately 2/3 human therapeutic concentrations) and above were recorded. These neoplastic changes were progressions of non-neoplastic changes related to hepatic enzyme induction observed in animal toxicity studies. Enzyme induction has not been observed following bicalutamide administration in man. There were no tumorigenic effects suggestive of genotoxic carcinogenesis.

A comprehensive battery of both *in vitro* and *in vivo* genotoxicity tests (yeast gene conversion, Ames, E. coli, CHO/HGPRT, human lymphocyte cytogenetic, mouse micronucleus, and rat bone marrow cytogenetic tests) has demonstrated that bicalutamide tablets do not have genotoxic activity. Administration of bicalutamide tablets may lead to inhibition of spermatogenesis. The long-term effects of bicalutamide tablets on male fertility have not been studied.

In male rats dosed at 250 mg/kg/day (approximately 2 times human therapeutic concentrations), the precoat interval and time to successful mating were increased in the first pairing but had no effects on fertility following successful mating were seen. These effects were reversed by 7 weeks after the end of an 11-week period of dosing.

No effects on female rats dosed at 10, 50 and 250 mg/kg/day (approximately 2/3, 1 and 2 times human therapeutic concentrations, respectively) or their female offspring were observed. Administration of bicalutamide to pregnant females resulted in feminization of the male offspring leading to hypoplasia at all dose levels. Affected male offspring were also impacted.

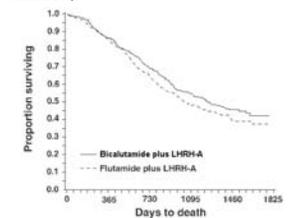
\*Based on a maximum dose of 50 mg/day of bicalutamide for an average 70 kg patient.

#### 14 CLINICAL STUDIES

**14.1 Bicalutamide Tablets 50 mg Daily in Combination with an LHRH-A** in a multicenter, double-blind, controlled clinical trial, 813 patients with previously untreated advanced prostate cancer were randomized to receive bicalutamide tablets 50 mg once daily (404 patients) or flutamide 250 mg (409 patients) 3 times a day, each in combination with LHRH analogs (either goserelin acetate implant or leuprolide acetate depot).

An analysis conducted after a median follow-up of 160 weeks was reached. 213 (52.7%) patients treated with bicalutamide tablets and LHRH analog therapy and 235 (57.5%) patients treated with flutamide-LHRH analog therapy had died. There was no significant difference in survival between treatment groups (see Figure 1). The hazard ratio for time to death (survival) was 0.87 (95% confidence interval 0.72 to 1.05).

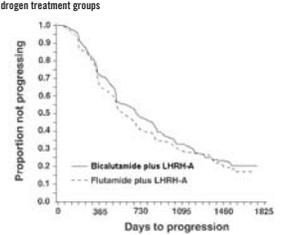
**Figure 1. The Kaplan-Meier Probability of Death for Both Antandrogen Treatment Groups**



There was no significant difference in time to objective tumor progression between treatment groups (see Figure 2). Objective tumor progression was defined as the appearance of any bone

metastases or the worsening of any existing bone metastases on bone scan attributable to metastatic disease, or an increase by 25% or more of any existing measurable extraosseal metastases. The hazard ratio for time to progression of bicalutamide tablets plus LHRH analog to that of flutamide plus LHRH analog was 0.93 (95% confidence interval, 0.79 to 1.10).

**Figure 2. Kaplan-Meier curve for time to progression for both antandrogen treatment groups**



Quality of life was assessed with self-administered patient questionnaires on pain, social functioning, emotional well being, vitality, activity limitation, bed disability, overall health, physical capacity, general symptoms, and treatment related symptoms. Assessment of the Quality of Life questionnaires did not indicate consistent significant differences between the two treatment groups.

#### 14.2 Safety Data from Clinical Studies Using Bicalutamide Tablets 150 mg

Bicalutamide tablets 150 mg are not approved for use either alone or with other treatments.

Two identical multicenter, randomized, open-label trials comparing bicalutamide tablets 150 mg daily monotherapy to castration were conducted in patients with locally advanced (T3-4, NX, MO) or metastatic (M1) prostate cancer.

#### Monotherapy:

##### M1 Group:

Bicalutamide tablets 150 mg daily are not approved for use in patients with M1 cancer of the prostate. Based on an interim analysis of the two trials for survival, the Data Safety Monitoring Board recommended that bicalutamide tablets treatment be discontinued in the M1 patients because the risk of death was 25% (HR 1.25, 95% CI 0.87 to 1.81) and 31% (HR 1.31, 95% CI 0.97 to 1.77) higher in the bicalutamide tablets-treated group compared to that in the castrated group, respectively.

##### Locally Advanced (T3-4, NX, MO) Group:

Bicalutamide tablets 150 mg daily are not approved for use in patients with locally advanced (T3-4, NX, MO) cancer of the prostate. Following discontinuation of all M1 patients, the trials continued with the T3-4, NX, MO patients until study completion. In the larger trial (N = 352), the risk of death was 25% (HR 1.25, 95% CI 0.92 to 1.71) higher in the bicalutamide tablets group and in the smaller trial (N = 140), the risk of death was 36% (HR 0.64, 95% CI, 0.39 to 1.03) lower in the bicalutamide tablets group.

In addition to the above two studies, there are three other on-going clinical studies that provide additional safety information for bicalutamide tablets 150 mg, a dose that is not approved for use. These are three multicenter, randomized, double-blind, parallel group trials comparing bicalutamide tablets 150 mg daily monotherapy (adjunct to previous therapy or under watchful waiting) with placebo, for death or time to disease progression, in a population of 8,113 patients with localized or locally advanced prostate cancer.

Bicalutamide tablets 150 mg daily are not approved for use as therapy for patients with localized prostate cancer who are candidates for watchful waiting. Data from a planned subgroup analysis of two of these trials in 1,627 patients with localized prostate cancer who were under watchful waiting, revealed a trend toward decreased survival in the bicalutamide tablets arm after a median follow-up of 7.4 years. There were 294 (27.3%) deaths in the bicalutamide tablets-treated patients versus 279 (22.0%) deaths in the placebo-treated patients (localized watchful waiting group) for a hazard ratio of 1.16 (95% CI 0.99 to 1.37).

#### 16 HOW SUPPLIED/STORAGE AND HANDLING

Bicalutamide Tablets, USP are available containing 50 mg of bicalutamide, USP.

The 50 mg tablets are white film-coated, round, unscored tablets debossed with **M** on one side of the tablet and **C17** on the other side. They are available as follows:

- NDC 0378-7017-93 bottles of 30 tablets
- NDC 0378-7017-01 bottles of 100 tablets
- NDC 0378-7017-05 bottles of 500 tablets

#### 16.1 Storage and Handling

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Dispense in a light, light-resistant container as defined in the USP using a child-resistant closure.

**PHARMACIST:** Dispense a Patient Information Leaflet with each prescription.

Mylan Pharmaceuticals Inc.  
Morgantown, WV 26505

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#### 17 PATIENT COUNSELING INFORMATION

Patients should be informed that therapy with bicalutamide tablets and the LHRH analog should be started at the same time and that they should not interrupt or stop taking these medications without consulting their physician.

During treatment with bicalutamide tablets, somnolence has been reported, and those patients who experience this symptom should observe caution when driving or operating machinery.

Patients should be informed that diabetes, or loss of glycemic control in patients with preexisting diabetes has been reported during treatment with LHRH agents. Consideration should therefore be given to monitoring blood glucose in patients receiving bicalutamide tablets in combination with LHRH agonists.

#### PATIENT INFORMATION

##### BICALUTAMIDE TABLETS, USP

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#### What are bicalutamide tablets?

Bicalutamide tablets are a prescription medicine called an androgen receptor inhibitor, used in combination with luteinizing hormone-releasing hormone (LHRH) medicines to treat stage D<sub>2</sub> metastatic prostate cancer. It is not known if bicalutamide tablets are safe and effective in children.

#### Who should not take bicalutamide tablets?

- Do not take bicalutamide tablets if:
  - you are a woman.
  - you are allergic to any of the ingredients in bicalutamide tablets. See the end of this leaflet for a complete list of ingredients

#### What should I tell my healthcare provider before taking bicalutamide tablets?

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

- are a woman (see who should not take bicalutamide tablets)
- are pregnant or think you may be pregnant
- 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 (poor blood sugar control has been reported in people taking bicalutamide tablets in combination with LHRH medicines)

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

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 prescribed.
- Take bicalutamide tablets at the same time everyday.
- Your treatment with bicalutamide tablets should start at the same time as your treatment with the LHRH medicine
- If you miss a dose do not take an extra dose, take the next dose at your regular time. Do not take two 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 Poison Control Center or go to the nearest hospital emergency room right away.
- Do not stop taking bicalutamide tablets unless your healthcare provider tells you.
- Your healthcare provider may do blood tests while you take bicalutamide tablets
- Your prostate cancer may get worse while taking 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.

#### What should I avoid while taking bicalutamide tablets?

Driving and operating machinery. Do not drive, operate machinery, or do other dangerous activities until you know how bicalutamide tablets affect you.

#### What are the possible side effects of bicalutamide tablets?

Bicalutamide tablets can cause serious side effects. Get medical help right away, if you have:

- trouble breathing with or without a cough or fever. Some people who take bicalutamide tablets get an inflammation in the lungs called interstitial lung disease.
  - An allergic reaction. Symptoms of an allergic reaction include: itching of the skin, hives (raised bumps), swelling of the face, lips, tongue, throat, or trouble swallowing.
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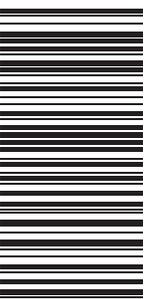
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