**abiraterone** (a-bi-ra-te-rone)

**Classification**
Therapeutic: antineoplastics
Pharmacologic: enzyme inhibitors

**Pregnancy Category** X

**Indications**
With prednisone in the treatment of metastatic castration-resistant prostate cancer.

**Action**
Inhibits the enzyme 17α-hydroxylase/C17,20-lyase, which is required for androgen production. May also result in increased mineralocorticoid production.

**Therapeutic Effects:** Decreased androgen production with decreased spread of androgen-sensitive prostate cancer.

**Pharmacokinetics**

**Absorption:** Hydrolyzed to its active compound following oral administration.

**Distribution:** Unknown.

**Protein Binding:** 99%.

**Metabolism and Excretion:** Metabolized by esterases to inactive compounds; eliminated primarily in feces as unchanged drug and metabolites; 5% excreted in urine.

**Half-life:** 12 hr.

**TIME/ACTION PROFILE (blood level)**

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<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
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<tbody>
<tr>
<td>PO</td>
<td>unknown</td>
<td>2 hr</td>
<td>12 hr</td>
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**Contraindications/Precautions**

**Contraindicated in:** Severe hepatic impairment (Child-Pugh Class C); Pregnancy or potential to become pregnant (may cause fetal harm); Lactation.

**Use Cautiously in:** Cardiovascular disease (safety not established if LVEF < 50% or NYHA Class III or IV heart failure; Recent myocardial infarction; Ventricular arrhythmias; Electrolyte abnormalities or hypertension (correct/control prior to initiation); Pre-existing liver disease (dose modification required for Child-Pugh Class B); Stress, infection, trauma, acute disease processes (may result in adrenocortical insufficiency requiring additional corticosteroids).

**Adverse Reactions/Side Effects**

- Noted for combination treatment with prednisone
  - Resp: cough
  - CV: edema, hypertension
  - GI: diarrhea, dyspepsia
  - Derm: hot flush
  - Endo: adrenocortical insufficiency (due to concurrent prednisone)
  - F and E: hypokalemia
  - GU: nocturia, urinary frequency
  - MS: fracture, joint pain/discomfort

**Interactions**

**Drug-Drug:**

- Acts as an inhibitor of the CYP2D6 enzyme system; avoid concurrent use with agents that are substrates of CYP2D6, especially those with narrow therapeutic indices, including thioridazine and dextromethorphan; if concurrent use is necessary, dosage of substrate may be required. Abiraterone is a substrate of the CYP3A4 enzyme system. Concurrent use of strong CYP3A4 inhibitors including carbamazepine, phenobarbital, phenytoin, rifabutin, or rifampin should be avoided or undertaken with caution.

**Route/Dosage**

**PO (Adults):**
- 1000 mg once daily used in combination with 5 mg prednisone twice daily; Concurrent use of strong CYP3A4 inducer—1000 mg twice daily.

**Hepatic Impairment**

**PO (Adults):**
- Child-Pugh Class B—250 mg once daily with 5 mg prednisone twice daily.

**NURSING IMPLICATIONS**

**Assessment**

- Monitor BP and assess for fluid retention at least monthly. Control hypertension during therapy.

- Monitor for signs and symptoms of adrenocortical insufficiency (hypotension, weight loss, weakness, nausea, vomiting, anorexia, lethargy, confusion, restlessness), especially in patients under stress or who are withdrawn from or have decreased prednisone dose. Symptom may be masked by abiraterone.

- **Lab Test Considerations:** Monitor AST, ALT, and bilirubin prior to, every 2 wks for 3 mos, and monthly thereafter. If AST and/or ALT > 5x normal, discontinue.

**Patient Education**

- Instruct patient to take abiraterone with food to minimize GI upset.

- Advise patient to take abiraterone exactly as directed. Do not discontinue or change dose without checking with health care professional.

- Caution patient to use sunscreen and protective clothing to prevent sunburn.

- Advise patient to report side effects, signs of fluid retention, and signs of adrenocortical insufficiency to health care professional.

- Instruct patient to carry identification card stating he/she is taking abiraterone.

- Advise patient to read Patient Information before starting therapy and with each Rx refill. Inform health care professional if pregnancy is planned or suspected or if breastfeeding.
times upper limit of normal or bilirubin \( \geq 3 \) times upper limit of normal in patients with baseline moderate hepatic impairment, interrupt abiraterone. Following return of liver function to baseline or AST and ALT \( \geq 2.5 \) times upper limit of normal or bilirubin \( \geq 3.5 \) times upper limit of normal, may re-start at a reduced dose of 750 mg once daily. Monitor serum transaminases and bilirubin every 2 wks for 3 mos and monthly thereafter. If hepatotoxicity occurs, may re-start at 500 mg once daily following return to baseline or AST and ALT \( \geq 2.5 \) times upper limit of normal or bilirubin \( \geq 3.5 \) times upper limit of normal. If hepatotoxicity recurs at 500 mg dose, discontinue therapy. Following return of liver function to baseline or AST and ALT \( \geq 2.5 \) times upper limit of normal or bilirubin \( \geq 1.5 \) times upper limit of normal may re-start at a reduced dose of 500 mg once daily following return to baseline or AST and ALT \( \geq 2.5 \) times upper limit of normal or bilirubin \( \geq 1.5 \) times upper limit of normal. If hepatotoxicity recurs at 500 mg dose, discontinue therapy. May cause hypokalemia; control during therapy.

- Monitor serum potassium and sodium at least monthly during therapy. May cause hypokalemia; control during therapy.

- May cause triglycerides and phosphorous.

Potential Nursing Diagnoses

Activity intolerance

Implementation

- PO: Administer twice daily with prednisone on an empty stomach at least 2 hrs before or 1 hr after meals; food increases absorption. Swallow tablets whole with water, do not crush, break, or chew.

Patient/Family Teaching

- Instruct patient to take medication as directed and not to stop abiraterone or prednisone without consulting health care professional. If a dose is missed, take the following day; if more than 1 dose is missed, consult health care professional. Do not share medication with others, even if they have the same symptoms; may be dangerous.

- Instruct patient to notify health care professional of all Rx or OTC medications, vitamins, or herbal products being taken and to consult with health care professional before taking other medications.

- Advise patient to notify health care professional of side effects that are bothersome or persistent.

- Advise female patient to use effective contraception during therapy and for 1 wk after therapy and to notify health care professional immediately if pregnancy is suspected or if breast feeding. Male patients should use a condom and another form of contraception during sex with a woman of child-bearing potential during and for 1 wk after therapy. Pregnant women should not touch the tablets without wearing gloves.

- Explain need for continued follow-up exams and lab tests to assess possible side effects.

Evaluation/Desired Outcomes

- Decreased spread of androgen-sensitive prostate cancer.

Why was this drug prescribed for your patient?