

PATIENT INFORMATION
Abiraterone Acetate Tablets, USP
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Patient Information Leaflet available at www1.apotex.com/products/us

What are Abiraterone Acetate Tablets?

Abiraterone acetate tablets are a prescription medicine that is used along with prednisone. Abiraterone acetate tablets are used to treat men with prostate cancer that has spread to other parts of the body.

Abiraterone acetate tablets are not for use in women.

It is not known if abiraterone acetate tablets are safe and effective in females or children.

Before you take Abiraterone Acetate Tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have liver problems
- have diabetes
- have a history of adrenal problems
- have a history of pituitary problems
- are receiving any other treatment for prostate cancer are pregnant or plan to become pregnant. Abiraterone acetate tablets can cause harm to your unborn baby and loss of pregnancy (miscarriage). Females who are or may become pregnant should not handle abiraterone acetate tablets uncoated tablets or other Abiraterone acetate tablets if broken, crushed, or damaged without protection, such as gloves.
- have a partner who is pregnant or may become pregnant.
 - Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment with abiraterone acetate tablets and for 3 weeks after the last dose of abiraterone acetate tablets.

are breastfeeding or plan to breastfeed. It is not known if abiraterone acetate passes into your breast milk.

Tell your healthcare provider about all the medicines you take or treatments you receive, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Abiraterone acetate can interact with many other medicines.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed abiraterone acetate tablets.

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take Abiraterone Acetate Tablets?

- Take abiraterone acetate tablets and prednisone exactly as your healthcare provider tells you.
- Take your prescribed dose of abiraterone acetate tablets 1 time a day.
- Your healthcare provider may change your dose if needed.
- **Do not change or stop taking your prescribed dose of abiraterone acetate tablets or prednisone without talking with your healthcare provider first.**
- Take abiraterone acetate tablets on an empty stomach, at least one hour before or at least two hours after a meal. **Do not take abiraterone acetate tablets with food.** Taking abiraterone acetate tablets with food may cause more of the medicine to be absorbed by the body than is needed and this may cause side effects.
- Swallow abiraterone acetate tablets whole. Do not crush or chew tablets.
- Take abiraterone acetate tablets with water.
- If you miss a dose of abiraterone acetate tablets or prednisone, take your prescribed dose the following day. If you miss more than 1 dose, tell your healthcare provider right away.
- Your healthcare provider will do blood tests to check for side effects.

What are the possible side effects of Abiraterone Acetate Tablets?

Abiraterone Acetate Tablets may cause serious side effects including:

- **High blood pressure (hypertension), low blood potassium levels (hypokalemia), fluid retention (edema), and irregular heartbeats can happen during treatment with abiraterone acetate tablets.** This can be life threatening. To decrease the chance of this happening, you must take prednisone with abiraterone acetate tablets exactly as your healthcare provider tells you. Your healthcare provider will check your blood pressure, do blood tests to check your potassium levels, and check for any signs and symptoms of fluid retention every month during treatment with abiraterone acetate tablets.

Tell your healthcare provider if you get any of the following symptoms:

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|--------------------------------|---------------------------------|
| ○ Dizziness | ○ confusion |
| ○ fast or irregular heartbeats | ○ muscle weakness |
| ○ feel faint or lightheaded | ○ pain in your legs |
| ○ headache | ○ swelling in your legs or feet |
- **Adrenal problems** may happen if you stop taking prednisone, get an infection, or are under stress.
 - **Severe liver problems.** You may develop changes in liver function blood test. Your healthcare provider will do blood tests to check your liver before treatment with abiraterone acetate tablets and during treatment with abiraterone acetate tablets. Liver failure may occur, which can lead to death. Tell your healthcare provider if you notice any of the following changes:
 - yellowing of the skin or eyes
 - darkening of the urine
 - severe nausea or vomiting

Increased risk of bone fracture and death when abiraterone acetate tablets and prednisone or prednisolone, is used in combination with a type of radiation called radium Ra 223 dichloride. Tell your healthcare provider about any other treatments you are taking for prostate cancer.

- **Severe low blood sugar (hypoglycemia).** Severe low blood sugar with abiraterone acetate can happen in people who have diabetes and take certain antidiabetic medicines. You and/or your healthcare provider should check your blood sugar levels regularly during treatment with abiraterone acetate and after you stop treatment. Your healthcare provider may also need to change the dose of your antidiabetic medicines. Signs and symptoms of low blood sugar may include:

- headache
- drowsiness
- weakness
- dizziness
- confusion
- irritability
- hunger
- fast heart beat
- sweating
- feeling jittery

The most common side effects of abiraterone acetate include:

- feeling very tired
- joint pain
- high blood pressure
- nausea
- swelling in your legs or feet
- low blood potassium levels
- hot flushes
- diarrhea
- vomiting
- infected nose, sinuses, or throat (cold)
- cough
- headache
- low red blood cells (anemia)
- high blood cholesterol and triglycerides
- high blood sugar levels
- certain other abnormal blood tests

Abiraterone acetate tablets may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of abiraterone acetate. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Abiraterone Acetate Tablets?

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

Keep Abiraterone Acetate Tablets and all medicines out of the reach of children.

General information about Abiraterone Acetate Tablets.

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

You can ask your healthcare provider or pharmacist for information about abiraterone acetate tablets that is written for health professionals.

For more information contact Apotex Corp. at 1-800-706-5575.

What are the ingredients of Abiraterone Acetate Tablets?

Active ingredient: abiraterone acetate

Inactive ingredients: colloidal silicon dioxide, crospovidone, lactose monohydrate, magnesium stearate, and sodium lauryl sulfate.

This Patient Information has been approved by the U.S. Food and Drug Administration.

APOTEX INC.

Abiraterone Acetate Tablets, USP

250 mg

Manufactured by:

Apotex Inc.
Toronto, Ontario
Canada M9L 1T9

Manufactured for:

Apotex Corp.
Weston, Florida
USA 33326

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