

How ZYTIGA® (abiraterone acetate) Works

ZYTIGA® Inhibits Androgen Production at 3 Sources—Including the Tumor Itself

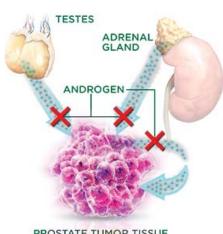
Oral, once-daily ZYTIGA® works by interrupting the androgen-making process at an important step. ZYTIGA® inhibits a key step in androgen production at three sources: the testes, the adrenal glands, AND the tumor itself. Watch the following videos to learn How ZYTIGA® Works:



How ZYTIGA® Works

You may be aware that the male body naturally produces hormones called androgens . The most well known androgen in men is testosterone. For men with mCRPC, androgens play a role in fueling the tumor. While not the only source, androgen is produced primarily in the testes and some is also produced by the adrenal glands, which are located above the kidneys. We know now that the tumor itself is also a source of androgen production. While there are other key factors that contribute to the disease, androgen is one such factor.





PROSTATE TUMOR TISSUE

ZYTIGA® may cause serious side effects including:

• High blood pressure (hypertension), low blood potassium levels (hypokalemia), and fluid retention (edema).

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

- Dizziness
- Fast heartbeats
- Feel faint or lightheaded
- Headache
- Confusion
- Muscle weakness
- Pain in your legs
- Swelling in your legs or feet

Oral, once-daily ZYTIGA® works by interrupting the androgen-making process at an important step.

Talk with your doctor to see if ZYTIGA® is right for you.

Important Safety Information

Who should not take ZYTIGA® (abiraterone acetate)?

Do not take ZYTIGA® if you are pregnant or may become pregnant. ZYTIGA® may harm your unborn baby. Women who are pregnant or who may become pregnant should not touch ZYTIGA® without protection, such as gloves.



Find authenticated court documents without watermarks at docketalarm.com.

ZYTIGA® is not for use in women or children. Keep ZYTIGA® and all medicines out of the reach of children.

Before you take ZYTIGA®, tell your healthcare provider if you:

- Have heart problems
- · Have liver problems
- · Have a history of adrenal problems
- · Have a history of pituitary problems
- · Have any other medical conditions
- Plan to become pregnant (See "Who should not take ZYTIGA®?")
- Are breastfeeding or plan to breastfeed. It is not known if ZYTIGA® passes into your breast milk. You and your healthcare provider should decide if
 you will take ZYTIGA® or breastfeed. You should not do both. (See "Who should not take ZYTIGA®?")
- Take any other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ZYTIGA® can interact with many other medicines.

If you are taking ZYTIGA®:

- Take ZYTIGA® and prednisone exactly as your healthcare provider tells you.
- Take your prescribed dose of ZYTIGA® one time a day. Your healthcare provider may change your dose if needed.
- . Do not stop taking your prescribed dose of ZYTIGA® or prednisone without talking to your healthcare provider first.
- Take ZYTIGA® on an empty stomach. **Do not take ZYTIGA® with food**. Taking ZYTIGA® with food may cause more of the medicine to be absorbed by the body than is needed and this may cause side effects.
- No food should be eaten 2 hours before and 1 hour after taking ZYTIGA®.
- Swallow ZYTIGA® tablets whole. Do not crush or chew tablets.
- · Take ZYTIGA® tablets with water.
- Your healthcare provider will do blood tests to check for side effects.
- Men who are sexually active with a pregnant woman must use a condom during and for one week after treatment with ZYTIGA®. If their female partner may become pregnant a condom and another form of birth control must be used during and for one week after treatment with ZYTIGA®. Talk with your healthcare provider if you have any questions about birth control.
- If you miss a dose of ZYTIGA® or prednisone, take your prescribed dose the following day. If you miss more than 1 dose, tell your healthcare provider right away.

ZYTIGA® may cause serious side effects including:

. High blood pressure (hypertension), low blood potassium levels (hypokalemia), and fluid retention (edema).

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

- Dizziness
- Fast heartbeats
- Feel faint or lightheaded
- Headache
- Confusion
- Muscle weakness
- Pain in your legs
- · Swelling in your legs or feet
- · Adrenal problems may happen if you stop taking prednisone, get an infection, or are under stress.
- Liver problems. You may develop changes in liver function blood tests. Your healthcare provider will do blood tests to check your liver before treatment with ZYTIGA® and during treatment with ZYTIGA®. 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

The most common side effects of ZYTIGA® include:

- Weakness
- · Joint swelling or pain
- Swalling in your logs or foo



- · Hot flushes
- Diarrhea
- Vomiting
- Cough
- High blood pressure
- · Shortness of breath
- · Urinary tract infection
- Bruising
- · Low red blood cells (anemia) and low blood potassium levels
- · High blood sugar levels, high blood cholesterol and triglycerides
- · Certain other abnormal blood tests

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 ZYTIGA®.
FOR MORE INFORMATION, ASK YOUR HEALTHCARE PROVIDER OR PHARMACIST.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ZYTIGA® can interact with other medicines.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed ZYTIGA®.

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.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088@ (1-800-332-1088@).

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WHAT IS ZYTIGA®?

ZYTIGA® (abiraterone acetate) is a prescription medicine that is used along with prednisone. ZYTIGA® is used to treat men with castration-resistant prostate cancer (prostate cancer that is resistant to medical or surgical treatments that lower testosterone) that has spread to other parts of the body.

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