

Abiraterone acetate (conventional) (Zytiga)

About This Medicine

ABIRATERONE (a bir A ter one) treats prostate cancer. It works by decreasing levels of the hormone testosterone in the body. This prevents prostate cancer cells from spreading or growing. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Decrease in the number of white blood cells and/or red blood cells. This may raise your risk of infection or make you tired and weak.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Tiredness
- Swelling of the hands, feet, or any other part of the body
- Hot flashes or sudden skin flushing may happen. You may also feel warm or red.
- Changes in your liver function
- Increase in your cholesterol level and triglycerides
- Blood sugar levels may change
- Decreased level of potassium in your blood
- Pain in the joints
- Headache
- Cough
- Upper respiratory tract infection
- High blood pressure

Note: Each of the side effects above was reported in 10% or greater of people treated with abiraterone acetate (Zytiga). All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions



- Severe high blood pressure
- Severe low potassium, which can cause abnormal heartbeats and be life-threatening.
- Severe swelling and/or weight gain
- Changes to the adrenal glands that may affect hormone production
- Changes in your liver function, which may be life-threatening.
- Increased risk of bone fracture and death when abiraterone acetate (Zytiga) and prednisone or prednisolone is used in combination with radium Ra 223 dichloride
- Increased risk of low blood sugar in patients taking certain types of medicines that treat type 2 diabetes mellitus.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

Important information

- Abiraterone acetate (Zytiga) is usually taken in combination with prednisone. Some people may
 also be taking a GnRH analog medicine. Follow your care team's instructions for how to take your
 medicines. Do not stop taking your medicines without consulting your care team.
- Do not substitute the micronized abiraterone product (Yonsa) for the conventional product (Zytiga), or the conventional product (Zytiga) for the micronized product (Yonsa).

How to Take Your Medicine

- Swallow this medicine whole with water on an empty stomach. Do not eat food 2 hours before or 1 hour after taking this medicine. Do not crush or chew tablets.
- **Missed dose**: If you miss a dose of abiraterone acetate (Zytiga), take your next dose at the regular time the following day. Do not take 2 doses at the same time and do not double up on the next dose. If you miss more than one dose, call your care team.
- **Overdosage**: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling**: Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- Individuals that are pregnant or are trying to become pregnant should not handle abiraterone acetate (Zytiga) without protection such as gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage**: Store this medicine in the original container at room temperature. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have



take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicine that can lessen or stop your diarrhea.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day.
 Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diabetes, keep good control of your blood sugar level. Tell your care team if your glucose levels are higher or lower than normal.
- Keeping your pain under control is important to your well-being. Please tell your care team if you
 are experiencing pain.

Food and Medicine Interactions

- Abiraterone acetate (Zytiga) should be taken on an empty stomach.
- Check with your care team about all other prescription medicines and over-the-counter medicines
 and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this
 medicine as there are known medicine interactions with abiraterone acetate (Zytiga). Also, check
 with your care team before starting any new prescription or over-the-counter medicines, or dietary
 supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.
- There are known interactions of abiraterone acetate (Zytiga) with some medicines that treat type 2 diabetes mellitus. Ask your care team what precautions you should take.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

Fever of 100.4° F (38° C) or higher



- Chills
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- · Cough that is bothersome and/or coughing up yellow, green, or bloody mucus
- Wheezing and/or trouble breathing
- A headache that does not go away
- · Blurry vision or other changes in eyesight
- · Tiredness that interferes with your daily activities
- · Feeling dizzy or lightheaded
- Confusion
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Loss of appetite or unexplained weight loss
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Signs of possible low potassium levels: weakness, tiredness, muscle cramps, constipation
- Pain that does not go away or is not relieved by prescribed medicines
- Abnormal blood sugar
- Signs of high blood sugar: unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Signs of low blood sugar: feeling sleepy, increased hunger, sweating, shakiness, irritability
- Swelling of the hands, feet, or any other part of the body
- Muscle weakness or pain in your legs
- Weight gain of 5 pounds in one week (fluid retention)

Reproduction Warnings

- **Pregnancy warning**: This medicine can cause serious birth defects. If you can get your partner pregnant, use birth control while taking this medicine and for 3 months after the last dose. Tell your care team right away if you think your partner might be pregnant.
- **Fertility warning**: This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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