

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ZYTIGA**[®]

Abiraterone acetate tablets

Read this carefully before you start taking **ZYTIGA**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ZYTIGA**[®].

Serious Warnings and Precautions

- **ZYTIGA**[®] may cause **hypertension** (high blood pressure), **hypokalemia** (low blood potassium) and **peripheral edema** (swelling of the legs or hands caused by fluid retention). These will need to be treated before starting **ZYTIGA**[®]. Your healthcare professional will do tests to check these problems monthly.
- Tell your healthcare professional if you have a history of heart failure, heart attack, or other heart problems. This will help avoid side effects and ensure proper use of **ZYTIGA**[®].
- If you have moderate to serious liver problems, you should not take **ZYTIGA**[®].
- **ZYTIGA**[®] may cause **liver failure**, sometimes causing death.

What is **ZYTIGA[®] used for?**

ZYTIGA[®], is used with another drug called prednisone to treat adults with prostate cancer that has spread to other parts of the body. These adults must have:

- Mild or no symptoms after treatment with androgen deprivation therapy (ADT) that does not work.
or
- had cancer treatment with a drug called docetaxel after treatment of ADT that does not work.

ZYTIGA[®], is also used with another drug called prednisone and androgen deprivation therapy (ADT) to treat adults with prostate cancer that has spread to other parts of the body. These adults must have:

- newly confirmed case of hormone-sensitive high-risk prostate cancer and may have been treated with ADT for up to 3 months.

How does **ZYTIGA[®] work?**

ZYTIGA[®] works to stop your body from making a type of hormone called androgens. Androgens promote cancer cell growth. Therefore, **ZYTIGA**[®] can help slow the growth of prostate cancer.

What are the ingredients in **ZYTIGA[®]?**

Medicinal ingredient: Abiraterone acetate

Nonmedicinal ingredients:

ZYTIGA[®] 250 mg uncoated tablets: Colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate.

ZYTIGA[®] 500 mg film-coated tablets: Colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, silicified microcrystalline cellulose, and sodium lauryl sulfate. Tablet film coating: iron oxide black, iron oxide red, macrogol 3350, polyvinyl alcohol, talc, and titanium dioxide.

ZYTIGA[®] comes in the following dosage forms:

- Uncoated tablets, 250 mg
- Film-coated tablets, 500 mg

Do not use ZYTIGA[®] if:

- You are allergic to abiraterone acetate or any of the other ingredients of ZYTIGA[®] or the container.
- You are pregnant or might be pregnant.
- You are breastfeeding .

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZYTIGA[®]. Talk about any health conditions or problems you may have, including if you:

- have or have had high blood pressure, low blood potassium and irregular heartbeats
- have diabetes
- have or have had heart failure, heart attack, artery blood clots or other heart problems
- have liver problems
- have or have had adrenal (hormonal) problems
- will have surgery or had surgery
- have or had severe trauma or infections

Other warnings you should know about:

ZYTIGA[®] **must be taken on an empty stomach** since food can increase the blood level of ZYTIGA[®] and this may be harmful. Do not eat any solid or liquid food two hours before taking ZYTIGA[®] and at least one hour after taking ZYTIGA[®].

Liver Problems: ZYTIGA[®] can cause liver failure which can lead to death. Talk to your healthcare professional if you have yellowing of the skin or eyes, dark urine, or serious nausea or vomiting. These could be signs or symptoms of liver problems. You will have regular blood tests done before starting ZYTIGA[®], every two weeks for the first three months while taking ZYTIGA[®], and every month after. These blood tests will tell your healthcare professional how your liver is working.

Low blood sugar (hypoglycemia):

ZYTIGA® may affect your blood sugar levels if you have diabetes. Your blood sugar might drop if you take ZYTIGA® plus prednisone/prednisolone with drugs for diabetes, like pioglitazone or repaglinide. Your healthcare professional will check your blood sugar levels.

Muscle problems: ZYTIGA® might cause muscle problems including break down of damaged muscle (**rhabdomyolysis**). This can cause kidney failure.

See the “Serious side effects and what to do about them” table, below, for more information on these and other serious side effects.

Check-ups and testing: You will have regular visits with your healthcare professional, before, during and at the end of your treatment. They will:

- Check your blood pressure
- Do blood tests and physical exams

Fertility and Sexual Health:**Male patients**

- During your treatment with ZYTIGA®, use a condom along with another effective birth control method each time you have sex with a woman who is pregnant, may be pregnant or could get pregnant. Continue using condoms until 1 week after your last dose.
- If, during your treatment with ZYTIGA®, your sexual partner becomes pregnant or thinks she may be pregnant, tell your healthcare professional right away.

Male patients – fertility

- Treatment with ZYTIGA® may affect your ability to father a child. If you have questions about this, talk to your healthcare professional.

Females

- ZYTIGA® is not for use in women.
- ZYTIGA® may harm an unborn baby.
- Women who are pregnant or may be pregnant should not handle **ZYTIGA®** 250 mg uncoated tablets without protective gloves.

ZYTIGA® should not be used in patients under 18 years of age.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ZYTIGA®:

- medicines typically used to treat epilepsy (seizures) such as phenytoin, carbamazepine, phenobarbital
- medicines to treat bacterial infections such as rifampicin, rifabutin
- an herbal treatment for depression called St. John’s wort
- medicines used to treat diabetes, such as pioglitazone, repaglinide

- a medicine used to relieve coughs such as dextromethorphan.

How to take ZYTIGA®:

- Take exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- **Take on an empty stomach.** Do not eat any solid or liquid food two hours before taking ZYTIGA® and at least one hour after taking ZYTIGA®. Taking ZYTIGA® with food may harm to you.
- Swallow tablets whole with water. Do not break the ZYTIGA® tablets.
- Take **ZYTIGA®** for as long as your healthcare professional prescribes it. Do not stop taking this medicine unless your healthcare professional tells you to.
- Your healthcare professional will monitor your health. They may interrupt, reduce or stop your dose. This may occur based on your current health if you take certain other medications or if you have certain side effects.
- Take the prednisone exactly as your doctor has told you.

Usual dose:

Recommended adult dose: 1000 mg per day. To make this dose, take two 500 mg tablets or four 250 mg tablets once per day.

You will also receive treatment with another medicine, prednisone. Your healthcare professional will tell you how much of this medicine you will take and how to take it.

Overdose:

If you think you, or a person you are caring for, have taken too much Zytiga, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose of ZYTIGA® or prednisone, skip the missed dose. Take your next dose at the usual time on the next day.

If you miss more than one dose of ZYTIGA® or prednisone, talk to your healthcare professional right away.

What are possible side effects from using ZYTIGA®?

These are not all the possible side effects you may have when taking ZYTIGA®. If you experience any side effects not listed here, tell your healthcare professional.

- Joint swelling or pain, muscle pain
- Hot flushes
- Cough
- Diarrhea
- Fatigue
- Constipation

- Vomiting
- Insomnia
- High blood pressure
- Stomach upset / Indigestion
- Flu-like symptoms
- Weight gain
- Frequent urination
- Blood in urine
- Bone fractures including ribs)
- Rash and skin wounds
- Falls
- Bruising
- Headache
- Depression

Your healthcare professional will do blood tests, check your blood pressure and monitor your health during your treatment. These will tell your healthcare professional how ZYTIGA® is affecting your blood, blood sugar, adrenal system and liver.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Anemia (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness		✓	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations			✓
Hypokalemia (low level of potassium in the blood): Muscle weakness, muscle twitches or a pounding heart-beat, cramping, constipation, fatigue, tingling or numbness.			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Peripheral edema (swelling of legs or hands caused by fluid retention): Swollen hands, legs, ankles or feet			✓
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder and urethra): Burning or pain during urination, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine.		✓	
COMMON			
Angina (not enough oxygen to the heart muscle): discomfort in the shoulder, arm, back, throat, jaw or teeth; pain or pressure in the chest.		✓	
Arrhythmias, including QT prolongation and Torsades de Pointes (irregular heart beat disorders): feeling faint, lightheaded, chest pain, a racing heartbeat, a slow heartbeat, shortness of breath, sweating, weakness seizures, or a fluttering in your chest.		✓	
Heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Pneumonia (infection in the lungs): chest pain when you breath or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking chills, nausea, vomiting or diarrhea, shortness of breath		✓	
Tachycardia (rapid heart rate)		✓	
UNCOMMON			
Adrenal effects: body aches, fatigue, low blood pressure, light-headedness, loss of body hair, skin discolouration, unexplained weight loss		✓	
VERY RARE			
Hypoglycemia (low blood sugar): thirst, frequent urination, hunger, nausea and dizziness, fast heartbeat, tingling trembling, nervousness, sweating, low energy.		✓	
UNKNOWN			
Allergic alveolitis (lung allergic reaction): shortness of breath, cough, fatigue, chills, sweating		✓	
Dyspnea (shortness of breath)		✓	
Rhabdomyolysis (breakdown of damaged muscle): muscle weakness, muscle pain, muscle spasms, red-brown coloured urine		✓	
Liver Failure (serious disturbance of liver function): yellowing of the skin or eyes, darkening of the urine, or severe nausea or vomiting, confusion, fatigue		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Severe allergic reactions includes, but are not limited to difficulty swallowing or breathing, swollen face or lips, tongue or throat, or an itchy rash called urticaria.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for more information on how to report online, by mail or by fax: or • Calling toll-free at 1-866-234-2345 <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Store at 15–30°C. Keep out of the reach and sight of children.

Do not use ZYTIGA® after the expiry date which is stated on the label. The expiry date refers to the last day of the month.

Do not throw away any drugs via wastewater or household waste. Ask your pharmacist how to throw away drugs you no longer use.

If you want more information about ZYTIGA®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: For questions, concerns, or the full Product Monograph go to: www.janssen.com/canada or contact the manufacturer, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

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