

PART III: CONSUMER INFORMATION

Pr ZYTIGA®

Abiraterone acetate tablets, Mfr. Std.

This leaflet is Part III of a three-part "Product Monograph" published when ZYTIGA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ZYTIGA®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ZYTIGA®, in combination with prednisone, is used to treat prostate cancer that has spread to other parts of the body in:

- adult patients who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT)
or
- adult patients who have had prior cancer treatment with docetaxel after failure of ADT
or
- adult patients with newly diagnosed hormone-sensitive high-risk prostate cancer who may have received up to 3 months of prior ADT

Asymptomatic patients are defined as patients who may have no noticeable changes to health. Mildly symptomatic patients may show symptoms or changes in health such as bone pain or fatigue.

What it does:

ZYTIGA® works to stop your body from making androgens. This can slow the growth of prostate cancer. ZYTIGA® may help delay the decline in your daily activity levels and may help delay the need for drugs to treat your cancer pain.

When your prostate cancer spreads beyond the prostate to other parts of the body, this is known as metastatic prostate cancer or advanced cancer.

Androgens are a group of hormones, and testosterone belongs to this group. Testosterone is the main type of androgen. Androgens promote cancer cell growth. That is why it's so important to keep these hormones at "castrate levels" (extremely low levels), to stop the growth of cancer.

ZYTIGA® helps to block the production of even small amounts of androgens in the three places they are produced: in the testes, the adrenal glands and the prostate cancer tumor itself.

When it should not be used:

- If you are allergic (hypersensitive) to abiraterone acetate or any of the other ingredients of ZYTIGA®.
- ZYTIGA® should not be taken by women who are pregnant or might be pregnant.

- ZYTIGA® should not be taken by women who are nursing.

What the medicinal ingredient is:

Abiraterone acetate

What the nonmedicinal ingredients are:

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.

What dosage forms it comes in:

250 mg uncoated tablets and 500 mg film-coated tablets.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- ZYTIGA® may cause high blood pressure, low blood potassium and swelling (fluid retention).
- ZYTIGA® should be used with caution in patients with a history of heart failure, heart attack, or other heart problems.
- Patients with severe and moderate liver problems should not take ZYTIGA®.
- Cases of liver failure, some leading to death have been reported. (see below for more information).

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®.

BEFORE you use ZYTIGA® talk to your doctor or pharmacist if:

- you have or have had high blood pressure or low blood potassium
- you have or have had heart failure, heart attack, or other heart problems
- you have liver problems
- you have or have had adrenal problems

ZYTIGA® may affect your liver. Rarely, failure of the liver to function (called acute liver failure) may occur, which can lead to death. Talk to your doctor if you develop yellowing of the skin or eyes, darkening of the urine, or severe nausea or vomiting, as these could be signs or symptoms of liver problems. When you are taking ZYTIGA® your doctor will check your blood to look for any effects of ZYTIGA® on your liver.

ZYTIGA® may harm an unborn baby. While taking ZYTIGA® and for one week after the last dose of ZYTIGA®, male patients must use a condom and another effective birth control method when having sexual activity with a woman who is pregnant or can become pregnant.

Women who are pregnant or may become pregnant should not handle ZYTIGA® 250 mg uncoated tablets without protective gloves.

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

INTERACTIONS WITH THIS MEDICATION

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

Tell your physician if you are taking phenytoin, carbamazepine, rifampicin, rifabutin, phenobarbital, or St. John's wort because these medications may decrease the effect of ZYTIGA®. This may lead to ZYTIGA® not working as well as it should.

PROPER USE OF THIS MEDICATION

Always take ZYTIGA® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Usual dose:

The usual dose is two 500 mg tablet or four 250 mg tablets (1g) by mouth once a day.

ZYTIGA® must be taken 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 causes more of this medicine to be absorbed by the body than is needed and this may be harmful.
- Swallow the tablets whole with a glass of water.
- Do not break the tablets.
- ZYTIGA® is taken with a medicine called prednisone to help manage potential side effects such as fluid in your legs or feet and muscle weakness, muscle twitches or a pounding heart beat (palpitations) which may be signs of low blood potassium (see Side Effects section below). Take the prednisone exactly as your doctor has told you.

Overdose

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you forget to take ZYTIGA® or prednisone, take your normal dose the following day.

If you forget to take ZYTIGA® or prednisone for more than one day, talk to your doctor without delay.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ZYTIGA® can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Very Common (affects more than 1 in 10 people):

- Joint swelling or pain, muscle pain
- Hot flushes
- Cough
- Diarrhea
- Fatigue
- Constipation
- Vomiting
- Insomnia
- Anemia
- High blood pressure

Common (affects less than 1 in 10 people):

- High fat levels in your blood
- Liver function test increases
- Heart failure
- Upper and lower respiratory infection
- Stomach upset / Indigestion
- Flu-like symptoms
- Weight increase
- Urinary frequency
- Bone break (fracture)
- Presence of blood in your urine
- Rash and skin lesions
- Falls
- Bruising
- Headache
- Depression

Uncommon (affects less than 1 in 100 people):

- Adrenal gland problems

Reported from post-marketing with unknown frequency

- Lung irritation - Symptoms may include shortness of breath, cough and fatigue.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Very Common			
Muscle weakness, muscle twitches or a pounding heart beat (palpitations). These may be signs of low level of potassium in your blood.			✓
Swollen hands, legs, ankles or feet			✓
Burning on urination or cloudy urine (Urinary tract infection)		✓	
Common			
Chest pain		✓	
Irregular heartbeat (Heart beat disorder)		✓	
Rapid heart rate		✓	
Unknown			
Shortness of breath		✓	
Breakdown of muscle tissue and muscle weakness and/or muscle pain		✓	
Yellowing of the skin or eyes, darkening of the urine, or severe nausea or vomiting (Failure of the liver to function/ acute liver failure)		✓	

This is not a complete list of side effects. For any unexpected effects while taking ZYTIGA[®], contact your doctor or pharmacist.

HOW TO STORE IT

ZYTIGA[®] tablets should be stored 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.

Medicines should not be thrown away via wastewater or household waste. Throw away any unused product or waste material in accordance with local requirements. If you are not sure, ask your pharmacist how to throw away medicines no longer required. These measures will help to protect the environment.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

MORE INFORMATION

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.

This leaflet was prepared by Janssen Inc., Toronto, Ontario M3C 1L9

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