Medication Information Sheet

abiraterone (a-bi-RA-te-rone)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Zytiga®

Appearance: tablet in various colours and strengths

What is this medication for?

Used with prednisone or dexamethasone for treating prostate cancer

What should I do before I have this medication?

- Tell your doctor if you have/had significant medical condition(s), especially if you have / had:
 - · High blood pressure,
 - · Low potassium levels,
 - · Heart, liver or adrenal gland problems,
 - Any allergies, or if you cannot tolerate lactose.
- This drug contains a small amount of lactose. If you cannot tolerate lactose, talk to your doctor.

How will this medication affect sex, pregnancy and breastfeeding?

- The use of this medication in men may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if your partner is pregnant or becomes pregnant during treatment.
- While this may not be directly applicable to you, if there is ANY chance that your partner may become pregnant, you and your partner together must: ► Use 2 effective forms of birth control at the same time while taking this drug. Keep using birth control until 1 week after the last dose. Discuss with your healthcare team.
- This medication may affect fertility (ability to get pregnant)

How is this medication given?

- Abiraterone is usually taken once a day.
- This medicine is often used together with prednisone or dexamethasone. Take these exactly as

directed by your doctor. Do not stop taking abiraterone and prednisone/ dexamethasone without talking to your doctor first.

- Swallow abiraterone whole with a glass of water **on an empty stomach**. No solid or liquid food should be eaten for at least 2 hours before and for at least 1 hour after taking abiraterone.
- Taking this drug with meals causes more drug to be absorbed and may cause more side effects.
- If you miss a dose, skip this and take your next dose on the following day. Do not double the dose to make up for the forgotten one. If you miss more than 1 dose, talk to your doctor.

What else do I need to know while on this medication?

- This medication can interact with other medications and can result in the treatment not working as well or cause severe side effects.
- Make sure your health care team knows about all your medications (prescription, over-thecounter, herbals and supplements). Check with your health care team before starting or stopping any of them.
- Tell your doctor before you undergo surgery. Your doctor may adjust your corticosteroid dose if your body undergoes unusual stress such as surgery, major injuries or serious infections.
- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.

How should I safely store this medication?

- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- Since abiraterone may harm the unborn baby, women who are pregnant or who may become pregnant should handle abiraterone with gloves.

What are the side effects of this medication?

You may not have all of the side effects below. You may have side effects that are not listed.

Side effects and what to do	When to contact doctor?
More Common Side Effects (50 or more out of 100 people	e)
Abnormal cholesterol or fat levels in the blood Your doctor may check your cholesterol levels regularly with a blood test.	Contact your health care team if no improvement or
Total doctor may check your choicetor levele regularly war a blood tool.	if severe

Side effects and what to do	When to contact doctor?
Common Side Effects (25 to 49 out of 100 people)	
 You may have yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. Talk to your health care team if this happens. Your doctor may monitor your liver regularly with a blood test. 	Contact your health care team if no improvement or if severe
 Fatigue (tiredness) Be active and aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. Pace yourself, do not rush. Put off less important activities. Rest when you need to. Eat well and stay hydrated by drinking at least 6 to 8 glasses of water or other liquids every day (unless your doctor told you to drink more or less). Avoid driving or using machinery if you are feeling tired See our Fatigue pamphlet for more information. 	Contact your health care team if no improvement or if severe
 Headache; mild joint, muscle pain or cramps Take your pain medication as prescribed by your doctor. You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you. 	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
Common Side Effects (25 to 49 out of 100 people)	
 Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medication may increase bleeding risk. Rest often and try light exercise as it may help. 	
Mild swelling in arms and legs; puffiness To help prevent swelling: • Eat a low-salt diet. • Avoid tight fitting clothing. If you have swelling in your legs, keep your feet up when sitting.	Contact your health care team if no improvement or if severe
Salt imbalances It may cause muscle twitching, severe weakness or cramping, confusion and irregular heartbeat	Get emergency medical help right away

Side effects and what to do	When to contact doctor?	
Less Common Side Effects (10 to 24 out of 100 people)		
Constipation To help prevent constipation:	Contact your health care team if no improvement or	
 Drink more liquids and eat well. Drink at least 6 to 8 cups of liquids each day unless you have been told otherwise. Be Active. Exercise can help to keep you regular. Try to eat more fiber (e.g. fruits with skin, leafy greens and whole grains). If you take opioid pain medication, ask your health care team if eating more fibre is right for you. 	if severe	
To help treat constipation :		
If you have not had a bowel movement in 2 to 3 days you may need to take a laxative. Ask your health care team what to do.		
See the Constipation Pamphlet for more information.		

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
Hot flashes, feeling or wave of warmth You may sweat more or have trouble sleeping because of this.	Contact your health care team if no improvement or if severe
To help prevent hot flashes :	
 Avoid triggers such as spicy food, alcohol and caffeine (tea, coffee, and soft drinks), Exercise regularly. Ask your health care team what exercises are 	
appropriate for you before you start any new exercise.Quitting smoking may also help.	
If you have hot flashes :	
 Keep cool; dress lightly or in layers that you can easily remove and drink plenty of liquids unless you have been told otherwise. 	
Hot flashes may improve over time. Talk to your health care team if this is bothersome for you.	
Other symptoms of having low testosterone levels	
 Decreased sexual function or desire to have sex Breast swelling or tenderness Low energy Mood changes, depression Thinning of the bones and higher risk of fracture 	
Contact your health care team if these feelings bother you.	
Diarrhea	Contact your
May happen days to weeks after you get your treatment.	health care team if no improvement or if severe
If you have diarrhea :	ii severe
 Take anti-diarrhea medication if your health care team prescribed it. Avoid foods or drinks with artificial sweetener (e.g. chewing gum, "diet" drinks), coffee and alcohol. Eat many small meals and snacks instead of 2 or 3 large meals. Drink at least 6 to 8 cups of liquids each day. Talk to your health care team if you can't drink 6-8 cups of liquids each day when you have diarrhea. You may need special liquids with salt and sugar, called Oral Rehydration Therapy. 	
See the <u>Diarrhea</u> pamphlet for more information.	

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
 Check your blood pressure regularly. Your doctor may prescribe medication to treat high blood pressure. If you have a severe headache, severe dizziness, or if you faint get emergency help right away as it may be a sign your blood pressure is too high. 	Contact your health care team if no improvement or if severe
Cough; feeling short of breath You may have cough and feel short of breath without any signs of infection, such as a sore throat or a stuffed nose. Rarely this may be severe with chest pain, trouble breathing or coughing up blood. If this happens get medical help right away.	Contact your health care team if no improvement or if severe
Nausea and vomiting (generally mild) May occur in hours to days after your treatment. If you have nausea or vomiting: Take anti-nausea medication(s) as prescribed to you by your doctor. Drink clear liquids and have small meals. Get fresh air and rest. Do not eat spicy, fried foods or foods with a strong smell. Limit caffeine (e.g. coffee, tea) and alcohol. Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting. Also see Nausea & Vomiting pamphlet for more information.	Talk to your health care team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours or if severe
 Anemia (low red blood cells) You may feel more tired or weak than normal and have pale skin. This may occur in days to weeks after you start or receive your medication. Rest often and eat well. Light exercise, such as walking may help. You may need medication or a blood transfusion. If it is very bad, your doctor may ask you to stop the medication that is causing the low red blood cells. 	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
Heartburn; stomach upset To help prevent heartburn:	Contact your health care team if no improvement or
 Avoid fatty or spicy foods. Remain upright after eating. Drink clear liquids and eat small meals. 	if severe

Since abiraterone is usually used with a corticosteroid (for example, prednisone), you may also experience the following. Talk to your health care team about these:

- stomach upset or ulcers
- weight gain
- mood changes; trouble falling asleep
- high blood sugar
- muscle weakness
- cataracts
- thinning of the bones or fractures

Refer to the <u>prednisone</u> or <u>dexamethasone</u> patient information sheet for more details.

Other rare, but serious side effects are possible.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- irregular heartbeat, chest pain, fainting, swelling in legs/ankles/belly, shortness of breath
- severe tiredness, darkening of skin, weight loss, loss of appetite
- severe muscle pain or weakness, dark urine

For more links on how to manage your symptoms go to www.cancercareontario.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.