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?

• For treating prostate cancer along with another medication such as prednisone.

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 problems including irregular heartbeats,
 - Liver or adrenal gland problems,
 - Diabetes, or
 - Any allergies
- This drug contains a small amount of lactose. If you cannot have lactose, talk to your healthcare team.

Remember to:

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

How will this medication affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this medication may affect your sexual health.
- How this medication may affect your ability to have a baby, if this applies to you.
- Symptoms such as hot flashes.

This medication may harm an unborn baby. Tell your health care team if your partner becomes pregnant during treatment.

If there is any chance of pregnancy happening, you and your partner together must use 2
 effective forms of birth control at the same time until 1 week after your last dose. Talk to your
 health care team about which birth control options are best for you.

How is this medication given?

- This medication is usually taken once a day by mouth. Talk to your health care team about how and when to take your medication.
- Swallow whole with a glass of water.
- Take abiraterone on an empty stomach. Do not eat any solid or liquid food for at least 2 hours before and at least 1 hour after taking your dose.
- You may need to take more than 1 tablet to get the right dose.
- This medicine is often used together with another medication such as prednisone. Take these
 medications as instructed by your health care team. Check with your health care team before
 stopping any medications.
- If you forget to take a dose of your abiraterone:
 - If you forget to take a dose, take your next dose as scheduled. Do not take extra (double up) to make up for the missed dose.
 - If you forget to take a dose for more than 1 day, talk to your health care team about what to do.
- If you vomit (throw up) after taking your medication, talk to your health care team about what to do.
- If you take too much of your medication by accident, or if you think a child or a pet may have swallowed your medication, you must call the Ontario Poison Control Center right away at: 1-800-268-9017.

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

- Will this medication interact with other medications or natural health products?
 - This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment not work as well or cause severe side effects.
 - Tell your health care team about all of your:
 - prescription and over-the-counter (non-prescription) medications and all other drugs, such as cannabis/marijuana (medical or recreational)
 - natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
 - Check with your health care team before starting or stopping any of them.

What to DO while on this medication:

- DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.
- DO tell your health care team about any serious infections that you have now.

What NOT to DO while on this medication:

DO NOT smoke or drink alcohol while on treatment without talking to your health care team first.
 Smoking and drinking can make side effects worse and make your treatment not work as well.

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.

How to safely touch oral anti-cancer medications

If you are a patient:

- Wash your hands before and after touching your oral anti-cancer medication.
- Swallow each pill whole. Do not crush or chew your pills.

If you are a caregiver:

Wash your hands before and after touching the oral anti-cancer medication.

If there is a chance your partner may become pregnant:

- Wear nitrile or latex gloves when touching tablets, capsules or liquids.
- Wash your hands before putting on your gloves and after taking them off, even if your skin did not touch the oral anti-cancer medication.
- Throw out your gloves after each use. Do not re-use gloves.

What to do if oral anti-cancer medication gets on your skin or in your eyes

If medication gets on your skin:

- Wash your skin with a lot of soap and water.
- If your skin gets red or irritated, talk to your health care team.

If medication gets in your eyes:

 Rinse your eyes with running water right away. Keep water flowing over your open eyes for at least 15 minutes.

What are the side effects of this medication?

The following table lists side effects that you may have when getting abiraterone. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on abiraterone.

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Liver problems	Get emergency medical help right
(May be severe)	away
Your health care team may check your liver function with a blood test. The liver changes do not usually cause any symptoms.	
What to look for?	
 Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe. 	
What to do?	
If you have any symptoms of liver problems, get emergency medical help right away.	
Fatigue What to look for?	Talk to your health care team if it does not improve or if it is severe
 Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. 	
What to do?	
 Be active. 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. Ask family or friends to help you with things like housework, shopping, and 	
 child or pet care. Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). Avoid driving or using machinery if you are feeling tired. 	
Ask your health care team for the <u>Fatigue</u> pamphlet for more information.	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Mild joint, muscle pain or cramps What to look for?	Talk to your health care team if it does not improve
New pain in your muscles or joints, muscle cramps, or feeling achy.	or if it is severe
What to do?	
 Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed. Rest often and try light exercise (such as walking) as it may help. 	
Ask your health care team for the Pain pamphlet for more information.	
Mild swelling	Talk to your health care team if it
What to look for?	does not improve
 You may have mild swelling or puffiness in your arms and/or legs. Rarely, this may be severe. 	or if it is severe
What to do?	
To help prevent swelling:	
Eat a low-salt diet.	
If you have swelling:	
Wear loose-fitting clothing.	
 For swollen legs or feet, keep your feet up when sitting. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Constipation	Talk to your health care team if it
What to look for?	does not improve or if it is severe
Having bowel movements (going poo) less often than normal.	or it it is severe
Small hard stools (poo) that look like pellets.	
The need to push hard and strain to have any stool (poo) come out.	
Stomach ache or cramps.	
 A bloated belly, feeling of fullness, or discomfort. 	
 Leaking of watery stools (poo). 	
Lots of gas or burping.	
Nausea or vomiting.	
What to do?	
To help prevent constipation:	
 Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains. 	
 Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less. 	
Be Active. Exercise can help to keep you regular.	
 If you take opioid pain medication, ask your health care team if eating 	
more fibre is right for you.	
To help treat constipation:	
If you have not had a bowel movement in 2 to 3 days you may need to take	
a laxative (medication to help you poo) to help you have regular bowel	
movements. Ask your health care team what to do.	
Ask your health care team for the Constipation Pamphlet for more information.	
Changes to your hormone levels	Talk to your health care team if it
Your treatment causes changes in the levels of testosterone in your body. This can affect your mood, energy levels or physical appearance, among other things.	does not improve or if it is severe
You may have many of these symptoms or none at all. Your symptoms may also change at different times in your treatment.	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
What to look for?	
Hot flashes:	
 A hot flash feels like a sudden warmth in your upper body and face. It can happen quickly and with no warning. Your face may get flushed (turn red) and you may sweat more Hot flashes can cause you to have trouble sleeping 	
Other symptoms of having low testosterone levels:	
 Problems with erectile dysfunction (getting or keeping erections) or less desire to have sex Breast swelling or tenderness Low energy Mood changes, depression Thinning of the bones and higher risk of fracture High cholesterol and effects on your heart 	
What to do?	
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:	
 To keep cool, dress in light, cotton clothing or in layers that you can easily remove. Use a fan Drink plenty of water or other liquids (at least 6 to 8 cups) unless your health care team has told you to drink more or less. Lay a towel on top of your bed sheet before you sleep so you can change it easily if you sweat at night. 	
Hot flashes may improve over time. Talk to your health care team if this or any symptoms of low testosterone are bothersome for you.	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Diarrhea What to look for?	Talk to your health care team if no improvement after
Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment.	24 hours of taking diarrhea medication or if severe (more than
What to do?	7 times in one day)
If you have diarrhea:	
 Take anti-diarrhea medication if your health care team prescribed it or told you to take it. Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol, until your diarrhea has stopped. Eat many small meals and snacks instead of 2 or 3 large meals. Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. Talk to your health care team if your diarrhea does not improve after 24 hours of taking diarrhea medication or if you have diarrhea more than 7 times in one day. Ask your health care team for the <u>Diarrhea</u> pamphlet for more information.	
Too much or too little salt in your body	Get emergency medical help right
What to look for?	away for severe symptoms
 Muscle spasms, cramping, weakness, twitching, or convulsions. Irregular heartbeat, confusion or blood pressure changes. 	
What to do?	
Get emergency medical help right away for severe symptoms.	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
High blood pressure	Talk to your health care team if it
What to look for?	does not improve or if it is severe
 There are usually no signs of high blood pressure. Rarely, you may have headaches, shortness of breath or nosebleeds. 	
What to do?	
Check your blood pressure regularly.Your doctor may prescribe medication to treat high blood pressure.	
If you have a severe headache get emergency help right away as it may be a sign your blood pressure is too high.	
Infection	If you have a fever, try to contact your
What to look for?	health care team. If you are unable to
 If you feel hot or unwell (for example if you have chills or a new cough), you must check your temperature to see if you have a fever. Do not take medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen). Do not eat or drink anything hot or cold right before taking your temperature. 	talk to the team for advice, you MUST get emergency medical help right away
You have a fever if your temperature taken in your mouth (oral temperature) is:	
38.3°C (100.9°F) or higher at any time OR	
• 38.0°C (100.4°F) or higher for at least one hour.	
What to do?	
 Wash your hands often to prevent infection. Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist. Keep a digital thermometer at home so you can easily check for a fever. 	
If you have a fever:	
If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Cough and feeling short of breath	Talk to your health care team. If you
 What to look for? You may have a cough and feel short of breath. Symptoms that commonly occur with a cough are: 	are not able to talk to your health care team for advice,
 wheezing or a whistling breathing runny nose sore throat heartburn weight loss fever and chills Rarely this may be severe with chest pain, trouble breathing or coughing up blood. 	and you have a fever or severe symptoms, you MUST get emergency medical help right away
What to do?	
 Check your temperature to see if you have a fever. If you have a fever, try to talk to your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away. If you have a severe cough with chest pain, trouble breathing or you are coughing up blood, get medical help right away. 	
Trouble Sleeping Your medications may cause trouble sleeping. It may get better once your body gets used to the medication or when your treatment ends.	Talk to your health care team if it does not improve or if it is severe
What to look for?	
 You may find it hard to fall asleep or stay asleep. How well you sleep may change over your treatment. For example, you may have several nights of poor sleep followed by a night of better sleep. You may wake up too early or not feel well-rested after a night's sleep. You may feel tired or sleepy during the day. 	
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Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Nausea and vomiting	Talk to your healthcare team if
(Generally mild)	nausea lasts more than 48 hours or
What to look for?	vomiting lasts more than 24
 Nausea is feeling like you need to throw up. You may also feel lightheaded. You may feel nausea within hours to days after your treatment. 	hours or if it is severe
What to do?	
To help prevent nausea:	
 It is easier to prevent nausea than to treat it once it happens. If you were given anti-nausea medication(s), take them as prescribed, even if you do not feel like throwing up. 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 (like coffee, tea) and avoid alcohol. 	
If you have nausea or vomiting:	
 Take your rescue (as-needed) anti-nausea medication(s) as prescribed. Ask your health care team for the <u>Nausea & Vomiting</u> pamphlet for more information. Talk to your health care team if: 	
 nausea lasts more than 48 hours vomiting lasts more than 24 hours or if it is severe 	
Anemia (low red blood cells)	Talk to your health care team if it does not improve or if it is severe
What to look for?	
 You may feel more tired or weaker than normal. Pale skin and cold hands and feet. You may feel short of breath, dizzy or lightheaded. 	
This may occur in days to weeks after your treatment starts.	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
What to do?	
If your health care team has told you that you have anemia (low red blood cells):	
 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 need to make changes to your treatment regimen. 	
Heartburn; stomach upset; bloating	Talk to your health care team if it
What to look for?	does not improve
 Pain or burning in the middle or top part of your chest. It may get worse when you are lying down or bending over or when you swallow. A bitter or acidic taste in your mouth. 	or if it is severe
What to do?	
 Drink clear liquids and eat small meals. Do not eat acidic, fatty or spicy foods. Limit caffeine (like coffee, tea) and avoid alcohol. Avoid smoking or being around tobacco. Sit up or stand after eating. Do not lie down. Raise the head of your bed six to eight inches. You may need to use extra pillows to do this. 	
Bladder problems or infections	Talk to your health
What to look for?	care team. Get emergency medical help right away for severe symptoms
 Feeling like you need to pee badly all of a sudden. Pain in your belly or lower belly area or pain when peeing. If severe, you may have blood in your pee. 	
What to do?	
 Drink at least 6 to 8 cups (2 Litres) of liquids per day, unless your health care team has told you to drink more or less. Tell your health care team if your pee is red or if you have other symptoms of bladder problems. Get emergency help right away for severe symptoms. 	

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> 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:

- flushing, itchiness, rash, swollen lips, face or tongue, wheezing, chest and throat tightness
- irregular heartbeat, chest pain, fainting, swelling in legs/ankles/belly
- severe or unusual bone pain especially in your back, hips and wrist
- severe tiredness, darkening of skin, weight loss, loss of appetite
- · severe muscle pain or weakness, dark-coloured pee

Who do I contact if I have questions or need help?
My cancer health care provider is:
During the day I should contact:
Evenings, weekends and holidays:
Other Notes:

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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.