

Medication Information Sheet

apalutamide (a-pa-LOO-ta-mide)

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: Erleada®

Appearance: tablet

What is this medication for?

- For treating prostate cancer

What should I do before I have this medication?

- Tell your health care team if you have or had significant medical condition(s), especially if you have / had:
 - ◊ high blood pressure or high blood sugar
 - ◊ high levels of fat or cholesterol in your blood
 - ◊ heart disease or irregular heartbeat
 - ◊ risk of falls or broken bones
 - ◊ underactive thyroid (called hypothyroidism)
 - ◊ seizures, brain injury, stroke, or brain tumors (non-cancerous or cancerous) or
 - ◊ any allergies

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

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

- 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 until **3 months** after your last dose. Tell your health care team if your partner is pregnant or becomes pregnant during treatment.

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, with or without food. If you cannot swallow your medication whole, talk to your health care team about what to do.
- Take the dose at about the same time each day.
- If you miss a dose, take your normal dose as soon as possible on the same day. Go back to your regular schedule on the following day. You should not take 2 doses or extra tablets to make up the missed dose.
- If you vomit (throw up) after taking your medication, talk to your health care team about what to do.
- Apalutamide is usually taken with another medication known as a gonadotropin-releasing hormone (GnRH) analogue, unless you had a surgery to remove your testicles in order to lower the amount of testosterone in your body. Your healthcare professional will tell you exactly how and when to take apalutamide and the GnRH analogue.
- 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 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 wear shoes that have nonslip soles and some ankle support. Also try to stand up slowly after sitting or lying down to lower your chance of falling down.

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?

- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- Keep this medication in the original packaging at room temperature (15°C to 30°C) in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- If your apalutamide tablets are provided to you in a bottle, the bottle contains silica gel desiccant to help keep your medication dry. Do not remove desiccant from the bottle.

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 apalutamide. 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 apalutamide.

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Fatigue</p> <p>What to look for?</p> <ul style="list-style-type: none"> Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. <p>What to do?</p> <ul style="list-style-type: none"> 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. <p>Ask your health care team for the Fatigue pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>High blood pressure</p> <p>(May be severe)</p> <p>What to look for?</p> <ul style="list-style-type: none"> There are usually no signs of high blood pressure. Rarely, you may have headaches, shortness of breath or nosebleeds. <p>What to do?</p> <ul style="list-style-type: none"> Check your blood pressure regularly. Your doctor may prescribe medication to treat high blood pressure. <p>If you have a severe headache get emergency help right away as it may be a sign your blood pressure is too high.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Rash; dry, itchy skin</p> <p>(May be severe)</p> <p>What to look for?</p> <ul style="list-style-type: none"> You may have cracked, rough, flaking or peeling areas of the skin. Your skin may look red and feel warm, like a sunburn. Your skin may itch, burn, sting or feel very tender when touched. <p>What to do?</p> <p>To prevent and treat dry skin:</p> <ul style="list-style-type: none"> Use fragrance-free skin moisturizer. Protect your skin from the sun and the cold. Use sunscreen with UVA and UVB protection and a SPF of at least 30. Avoid perfumed products and lotions that contain alcohol. Drink 6 to 8 cups of non-alcoholic, non-caffeinated liquids each day, unless your health care team has told you to drink more or less. <p>Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Diarrhea</p> <p>What to look for?</p> <ul style="list-style-type: none"> Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. <p>What to do?</p> <p>If you have diarrhea:</p> <ul style="list-style-type: none"> 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. 	<p>Talk to your health care team if no improvement after 24 hours of taking diarrhea medication or if severe (more than 7 times in one day)</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> • 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. <p>Ask your health care team for the Diarrhea pamphlet for more information.</p>	
<p>Nausea and vomiting</p> <p>(Generally mild)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Nausea is feeling like you need to throw up. You may also feel light-headed. • You may feel nausea within hours to days after your treatment. <p>What to do?</p> <p>To help prevent nausea:</p> <ul style="list-style-type: none"> • 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. <p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take your rescue (as-needed) anti-nausea medication(s) as prescribed. • Ask your health care team for the Nausea & Vomiting pamphlet for more information. • Talk to your health care team if: <ul style="list-style-type: none"> ◦ nausea lasts more than 48 hours ◦ vomiting lasts more than 24 hours or if it is severe 	<p>Talk to your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours or if it is severe</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Low appetite, weight loss</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Loss of interest in food or not feeling hungry. • Weight loss. <p>What to do?</p> <ul style="list-style-type: none"> • Try to eat your favourite foods. • Eat small meals throughout the day. • You may need to take meal supplements to help keep your weight up. • Talk to your health care team if you have no appetite. <p>Ask your health care team for the Loss of Appetite pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Mild joint, muscle pain or cramps</p> <p>What to look for?</p> <ul style="list-style-type: none"> • New pain in your muscles or joints, muscle cramps, or feeling achy. <p>What to do?</p> <ul style="list-style-type: none"> • 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. <p>Ask your health care team for the Pain pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Changes to your hormone levels</p> <p>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.</p> <p>You may have many of these symptoms or none at all. Your symptoms may also change at different times in your treatment.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>What to look for?</p> <p>Hot flashes:</p> <ul style="list-style-type: none"> • 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 <p>Other symptoms of having low testosterone levels:</p> <ul style="list-style-type: none"> • 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 <p>What to do?</p> <p>To help prevent hot flashes:</p> <ul style="list-style-type: none"> • 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. <p>If you have hot flashes:</p> <ul style="list-style-type: none"> • 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. <p>Hot flashes may improve over time. Talk to your health care team if this or any symptoms of low testosterone are bothersome for you.</p>	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Bone pain; Bone loss or Bone fractures</p> <p>Your treatment may cause your bones to thin earlier than normal. Thin bones are weak and fragile. They may break easily from simple falls or movements. Your health care team may check your bone density (measure of how strong your bones are) with a bone scan.</p> <p>What to look for?</p> <ul style="list-style-type: none"> You may have severe or unusual bone pain especially in your back, hips and wrist. <p>What to do?</p> <p>To help prevent bone loss and fractures</p> <ul style="list-style-type: none"> Your health care team may ask you to change your diet, or may ask you to take calcium and vitamin D supplements, or other prescription medications. Talk to your health care team before taking any supplements. <p>Get emergency medical help if you experience severe bone pain or are unable to move as these may be signs of a bone fracture.</p> <p>See our Bone Health pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve. Get emergency medical help if you have severe bone pain or are unable to move.</p>
<p>Mild swelling</p> <p>What to look for?</p> <ul style="list-style-type: none"> You may have mild swelling or puffiness in your arms and/or legs. Rarely, this may be severe. <p>What to do?</p> <p>To help prevent swelling:</p> <ul style="list-style-type: none"> Eat a low-salt diet. <p>If you have swelling:</p> <ul style="list-style-type: none"> Wear loose-fitting clothing. For swollen legs or feet, keep your feet up when sitting. 	<p>Talk to your health care team if it does not improve or if it is severe</p>

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, shortness of breath, chest pain, fainting spells or swelling in your legs, ankles and belly
- Trouble with seeing, speaking or using your arms or legs
- Seizures
- Unusual weight gain which may be accompanied with: feeling tired or having low energy, dry skin, nails or hair that breaks easily, or sensitivity to cold
- Breathing problems, chest pain or cough up blood
- Redness, blistering and/or peeling of large areas of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, along with fever, chills, headache, cough, body aches or swollen glands

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:

April 2024 Updated/Revised "Less Common Side Effects" section

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.