

## 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), such as:
  - heart disease or irregular heartbeat
  - risk of falls or broken bones
  - history of seizures, brain injury, stroke, or brain tumors (non-cancerous or cancerous) or
  - any allergies
- People with cancer have a higher risk of getting other cancers or developing blood clots. Some cancer medications may increase these risks, especially if used for a long period of time. Discuss any concerns about this medication with your health care team.

### How will this medication affect sex, pregnancy and breastfeeding?

- The use of this medication may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or 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 for at least **3 months** after your last dose unless your health care team told you differently. Talk to your health care team to figure out the best method(s) for you and/or your partner
- This medication may affect fertility (ability to get your partner pregnant)

### How is this medication given?

The most updated information sheet version can be found on <https://www.cancercareontario.ca/drugs>  
 Additional symptom management information is available from <https://www.cancercareontario.ca/symptoms>  
 Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors.  
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- Swallow whole with a glass of water, with or without food.
- Take the dose at about the same time each day.
- Take it exactly as directed by your doctor. Make sure you understand the instructions.
- 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.
- 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 to take apalutamide and the GnRH analogue and also when you should take them.

## 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-the-counter, herbals and supplements). Check with your health care team before starting or stopping any of them.
- **For mild aches and pain or fever:**
  - If you feel unwell, take your temperature before taking any medications for pain or fever. They may hide a fever.
  - You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
  - Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding. Talk to your health care team before you start or stop these medications.
  - **Talk to your health care team or go to the closest emergency room right away if you have a fever.** See the [Fever](#) pamphlet for more information.
- 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.
- Some people have had seizures while taking this drug. The chance of seizures may be raised if you have certain brain blood vessel problems, take other drugs that may raise the chance of seizures, or if you have ever had seizures, brain injury, stroke, or brain cancer. Use caution when performing tasks or actions where passing out may cause harm to you or others. Talk with your

doctor.

## 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.

## 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?                                      |
|---|--|
| <b>Very Common Side Effects (50 or more out of 100 people)</b>  |  |
| <p><b>Abnormal cholesterol or fat levels in the blood</b></p> <p>Your doctor may check your cholesterol levels regularly with a blood test.</p>   | Contact your health care team if no improvement or if severe |
| <p><b>Anemia (low red blood cells)</b></p> <ul style="list-style-type: none"> <li>• You may feel more tired or weak than normal and have pale skin.</li> <li>• This may occur in days to weeks after you start or receive your medication.</li> <li>• Rest often and eat well.</li> <li>• Light exercise, such as walking may help.</li> <li>• You may need medication or a blood transfusion.</li> <li>• If it is very bad, your doctor may ask you to stop the medication that is causing the low red blood cells.</li> </ul> | Contact your health care team if no improvement or if severe |
| <p><b>High blood sugar</b></p> <ul style="list-style-type: none"> <li>• You may feel thirsty and pee more often.</li> <li>• Your doctor may check your blood sugar level. You may be advised to change your diet or take medication to treat high blood sugar.</li> <li>• Check your blood sugar regularly if you have diabetes.</li> </ul>   | Contact your health care team as soon as possible            |

| Side effects and what to do  | When to contact doctor?   |
|--|---|
| <b>Common Side Effects (25-49 out of 100 people)</b>   |   |
| <p><b>Low platelets in the blood</b></p> <ul style="list-style-type: none"> <li>• Watch for bleeding (such as unusual nosebleeds or bleeding from the gums) or bruising easily (this is rare).</li> <li>• Very rarely, severe symptoms can happen. If you notice black coloured stools (poo), red or pink coloured urine (pee), red or brown coloured mucus when you cough, severe headache/confusion or bleeding that will not stop, you need to talk to your health care team or go to the nearest emergency room right away.</li> </ul> <p>See the <a href="#">Low Platelet Count</a> pamphlet for more information.</p>  | <p>Get emergency medical help right away</p>                        |
| <p><b>Fatigue (tiredness)</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Pace yourself, do not rush. Put off less important activities. Rest when you need to.</li> <li>• 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).</li> <li>• Avoid driving or using machinery if you are feeling tired</li> </ul> <p>See our <a href="#">Fatigue</a> pamphlet for more information.</p> | <p>Contact your health care team if no improvement or if severe</p> |
| <p><b>Salt imbalances</b></p> <p>It may cause muscle twitching, severe weakness or cramping, confusion and irregular heartbeat.</p>  | <p>Get emergency medical help right away</p>                        |
| <p><b>High blood pressure</b></p> <ul style="list-style-type: none"> <li>• Check your blood pressure regularly. Your doctor may prescribe medication to treat high blood pressure.</li> <li>• If you have a severe headache, get emergency help right away as it may be a sign your blood pressure is too high.</li> </ul>   | <p>Contact your health care team if no improvement or if severe</p> |

| Side effects and what to do  | When to contact doctor?   |
|--|---|
| <b>Less Common Side Effects (10-24 out of 100 people)</b>  |   |
| <p><b>Rash; dry, itchy skin</b></p> <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><b>To prevent and treat dry skin,</b></p> <ul style="list-style-type: none"> <li>• Use skin moisturizer.</li> <li>• Protect your skin from the sun and the cold.</li> <li>• Use sunscreen with UVA and UVB protection and a SPF of at least 30.</li> </ul>   | <p>Contact your health care team if no improvement or if severe</p>   |
| <p><b>Diarrhea</b></p> <p>May happen days to weeks after you get your treatment.</p> <p><b>If you have diarrhea :</b></p> <ul style="list-style-type: none"> <li>• Take anti-diarrhea medication if your health care team prescribed it.</li> <li>• Avoid foods or drinks with artificial sweetener (e.g. chewing gum, “diet” drinks), coffee and alcohol.</li> <li>• Eat many small meals and snacks instead of 2 or 3 large meals.</li> <li>• 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.</li> </ul> <p>See the <a href="#">Diarrhea</a> pamphlet for more information.</p> | <p>Contact your health care team if no improvement or if severe</p>   |
| <p><b>Nausea (generally mild)</b></p> <p>May occur in hours to days after your treatment.</p> <p><b>If you have nausea:</b></p> <ul style="list-style-type: none"> <li>• Take anti-nausea medication(s) as prescribed to you by your doctor.</li> <li>• Drink clear liquids and have small meals. Get fresh air and rest.</li> <li>• Do not eat spicy, fried foods or foods with a strong smell.</li> <li>• Limit caffeine (e.g. coffee, tea) and alcohol.</li> <li>• Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting.</li> </ul> <p>Also see <a href="#">Nausea &amp; Vomiting</a> pamphlet for more information.</p>   | <p>Contact your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours</p> |
| <p><b>Low appetite</b></p> <ul style="list-style-type: none"> <li>• You may not feel like eating or you may lose weight.</li> </ul>  | <p>Contact your health care team if no improvement or</p>   |

| Side effects and what to do   | When to contact doctor?                                      |
|---|--|
| <b>Less Common Side Effects (10-24 out of 100 people)</b>   |  |
| <ul style="list-style-type: none"> <li>• Try to eat foods that you like and eat small meals throughout the day.</li> <li>• You may need to take meal supplements to help keep your weight up.</li> <li>• Talk to your health care team if you have a low appetite.</li> <li>• See our <a href="#">Loss of appetite</a> pamphlet for more information.</li> </ul>  | if severe  |
| <p><b>Mild joint or muscle pain</b></p> <ul style="list-style-type: none"> <li>• Take your pain medication as prescribed by your doctor.</li> <li>• You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you.</li> <li>• Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medication may increase bleeding risk.</li> <li>• Rest often and try light exercise as it may help.</li> </ul>  | Contact your health care team if no improvement or if severe |
| <p><b>Having falls</b></p> <ul style="list-style-type: none"> <li>• Symptoms that you may notice before a fall:             <ul style="list-style-type: none"> <li>◦ Dizziness</li> <li>◦ Light-headedness</li> <li>◦ Irregular or rapid, pounding heartbeats (palpitations)</li> <li>◦ Feeling unsteady at your feet</li> </ul> </li> <li>• If you have fallen, check your body for any pain or injuries.</li> <li>• Talk to your health care team if you have experienced a fall or near fall.</li> <li>• <b>Get emergency medical help if you feel confused, experience severe bone pain or are unable to move.</b></li> </ul>   | Contact your health care team if no improvement or if severe |
| <p><b>Hot flashes, feeling or wave of warmth</b></p> <p>You may sweat more or have trouble sleeping because of this.</p> <p><b>To help prevent hot flashes :</b></p> <ul style="list-style-type: none"> <li>• Avoid triggers such as spicy food, alcohol and caffeine (tea, coffee, and soft drinks),</li> <li>• Exercise regularly. Ask your health care team what exercises are appropriate for you before you start any new exercise.</li> <li>• Quitting smoking may also help.</li> </ul> <p><b>If you have hot flashes :</b></p> <ul style="list-style-type: none"> <li>• Keep cool; dress lightly or in layers that you can easily remove and drink plenty of liquids unless you have been told otherwise.</li> <li>• Hot flashes may improve over time. Talk to your health care team if this is bothersome for you.</li> </ul> | Contact your health care team if no improvement or if severe |

| Side effects and what to do   | When to contact doctor?   |
|---|---|
| <b>Less Common Side Effects (10-24 out of 100 people)</b>   |   |
| <p><b>Bone pain; Bone loss or Bone fractures</b> (long-term effect)</p> <ul style="list-style-type: none"> <li>• Watch for any severe or unusual bone pain especially in your back, hips and wrist.</li> <li>• Your doctor may monitor your bone density (measure of how strong your bones are), if needed.</li> </ul> <p><b>To help prevent bone loss and fractures</b>, your doctor may advise you to change your diet, take vitamin D supplements or other prescription medications. Talk to your doctor before taking any supplements.</p> <p><b>Get emergency medical help if you experience severe bone pain or are unable to move as these may be signs of a bone fracture.</b><br/>See our <a href="#">Bone Health</a> pamphlet for more information.</p> | <p>Contact your health care team if no improvement or if severe</p> |
| <p><b>Mild swelling in arms and legs; puffiness</b></p> <p><b>To help prevent swelling :</b></p> <ul style="list-style-type: none"> <li>• Eat a low-salt diet.</li> <li>• Avoid tight fitting clothing.</li> </ul> <p><b>If you have swelling in your legs</b>, keep your feet up when sitting.</p>   | <p>Contact your health care team if no improvement or if 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

**February 2021** Updated "What it is used for" section

For more links on how to manage your symptoms go to [www.cancercareontario.ca/symptoms](http://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

## apalutamide

*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.*