

ORAL CANCER TREATMENT EDUCATION



PASSION FOR PATIENTS
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APALUTAMIDE

Name of your medication

Generic name — apalutamide (A-puh-LOO-tuh-mide)
Brand name — Erleada™ (er-LEE-duh)

Common uses

Apalutamide is used to treat metastatic castration-sensitive and non-metastatic castration-resistant prostate cancer. Apalutamide may also be used for other treatments.

Dose and schedule

Taking apalutamide as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of apalutamide is 240 milligrams (240 mg) to be taken by mouth at a scheduled time once a day.
- Apalutamide can be taken with or without food but at the same time each day.
- Apalutamide should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow apalutamide, talk to your care provider or pharmacist for possible options.
- If you miss a dose of apalutamide, **do not** take an extra dose or two doses at one time. Simply take your dose as soon as you remember on that day and then take your next dose at the regularly scheduled time. Be sure to write down if you miss a dose and let your care provider know about any missed doses.

Drug and food interactions

- Apalutamide has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle apalutamide with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store apalutamide at room temperature (68°F–77°F) in a dry location away from light.
- Keep apalutamide out of reach of children and pets.
- Leave apalutamide in the provided packaging until it is ready to be taken.

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- Whenever possible, you should give apalutamide to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the apalutamide to you, they also need to follow these steps.
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the apalutamide from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- A daily pill box or pill reminder is **not** recommended to be used with apalutamide.
- If you have any unused apalutamide, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of apalutamide.
- If you are traveling, put your apalutamide's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Side Effects of Apalutamide

Below are common side effects that have been known to happen in about one third or more of patients taking apalutamide are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> • High cholesterol levels • High glucose levels • High tryglyceride levels • High potassium levels 	<p>Changes in some lab values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs or feet • Red- or brown-colored urine

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Possible Side Effect	Management
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is okay to rest as needed. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>
<p>Fatigue</p>	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.

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Possible Side Effect	Management
Rash or itchy skin	<ul style="list-style-type: none">• Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose fitting clothing.• Avoid using perfumes and cologne as these products may increase rash symptoms.• Avoid being in the heat for long periods of time.• Your provider may recommend an over-the-counter antihistamine or a topical cream.• Sunlight can make symptoms worse.• Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV (ultraviolet) radiation occurs between the hours of 10 am and 4 pm.• Wear long-sleeved clothing, with UV protection if possible.• Wear broad-brimmed hats.• Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle.• Use lip balm with at least SPF 30.

Serious side effects of apalutamide

- Apalutamide can cause bones to weaken and may increase your risk for falls and fractures. Your provider may prescribe medication to help prevent fractures.
- Apalutamide may make it more likely that you have a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harms. Seek medical attention right away if you have symptoms of a seizure and inform your care provider.
- Apalutamide may cause narrowing of arteries in your heart. Contact your care team if you have shortness of breath or chest pain.
- Apalutamide can increase your risk of having a stroke. It is important to know the signs and symptoms of a stroke. Pay attention to when the signs and symptoms begin, and call 911 immediately at the first sign of a stroke.
- Rarely, apalutamide can cause severe skin reactions, including Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening. Seek emergency care if you have a severe rash or a rash on your mouth, eyes, or genitals.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Apalutamide remains in your body for several days after it is taken, and some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take apalutamide, it is important to know the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.

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- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or apalutamide with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Men who have a pregnant partner should use a condom during intercourse, both during therapy and for a minimum of 3 months after the last dose of apalutamide.
- Men should use effective contraception to avoid getting a woman pregnant and should avoid donating sperm during treatment and for 3 months after treatment is complete.
- Effective contraception could include 1 or more of the following: barrier methods, etc.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care provider.

Obtaining medication

- Talk with your care provider about the process for obtaining your apalutamide.

(PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

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Additional resources

Product website: www.erleada.com

Product prescribing information:

www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ERLEADA-pi.pdf

Product resources: www.janssencarepath.com/hcp/erleada

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Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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