

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrERLEADA® apalutamide tablets

Read this carefully before you start taking **ERLEADA®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ERLEADA®**.

What is **ERLEADA®** used for?

ERLEADA® is used to treat prostate cancer that

- has spread to other parts of the body and still responds to a medicine or surgery that lowers testosterone
- has not spread to other parts of the body, and no longer responds to a medicine or surgery that lowers testosterone.

ERLEADA® has not been studied in patients with low risk of the cancer spreading to other parts of the body. Talk to your healthcare professional if you have questions about this.

How does **ERLEADA®** work?

ERLEADA® contains apalutamide. Apalutamide is in a class of medicines called androgen receptor inhibitors. It works by blocking the activity of androgens (hormones like testosterone) to slow the spread of your prostate cancer and the start of your disease symptoms.

What are the ingredients in **ERLEADA®**?

ERLEADA® 60 mg tablet

Medicinal ingredient: apalutamide

Non-medicinal ingredients: colloidal anhydrous silica, croscarmellose sodium, hydroxypropyl methylcellulose-acetate succinate, iron oxide black, iron oxide yellow, magnesium stearate, microcrystalline cellulose, microcrystalline cellulose (silicified), polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

ERLEADA® 240 mg tablet

Medicinal ingredients: apalutamide

Non-medicinal ingredients: colloidal anhydrous silica, croscarmellose sodium, glyceryl monocaprylocaprate, hydroxypropyl methylcellulose-acetate succinate, iron oxide black, macrogol poly (vinyl alcohol) grafted copolymer, magnesium stearate, microcrystalline cellulose (silicified), polyvinyl alcohol, talc, titanium dioxide.

ERLEADA® comes in the following dosage forms:

tablet, 60 mg, 240 mg

Do not use ERLEADA® if:

- you are allergic to apalutamide or to any ingredient in the medicine, including any non-medicinal ingredient, or component of the container.
- you are pregnant or can get pregnant. ERLEADA® may harm your unborn baby.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ERLEADA®. Talk about any health conditions or problems you may have, including if you:

- have high blood pressure, high blood sugar levels or high levels of fat in your blood (called dyslipidemia).
- have a history of heart disease including a known history of an abnormal electrical signal called “QT interval prolongation”.
- have a risk of falls or broken bones.
- have a history of seizures, brain injury, stroke, or brain tumors (non-cancerous or cancerous).
- have ever had a severe rash over the body, usually with fever, swollen lymph nodes and effects on blood cells and organs (drug reaction with eosinophilia and systemic symptoms or DRESS), or a severe skin rash or skin peeling, blistering and/or mouth sores (Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis)

Other warnings you should know about:

Women, infants, and children: ERLEADA® is not for use in women and children.

Men:

ERLEADA® can harm your unborn baby or can make your partner lose the baby.

- If your partner is pregnant, you must use a condom whenever you have sex during your treatment with ERLEADA® and for 3 months after the last dose.
- If your sexual partner is not pregnant but may become pregnant, you **must** use a condom and another form of highly effective birth control whenever you have sex during your treatment and for 3 months after treatment. Talk with your healthcare professional if you have questions about birth control.
- If your sexual partner becomes pregnant while you are taking ERLEADA®, **tell your healthcare professional right away.**
- you must **not** donate sperm during your treatment and for 3 months after your last dose of ERLEADA®.

Monitoring, laboratory, and blood tests:

Your healthcare professional may do blood tests before you take ERLEADA® and/or during treatment. Your healthcare professional may check for:

- risks for falls and broken bones
- signs of brain problems (stroke or mini-stroke)
- signs of heart disease
- signs of low thyroid levels (hypothyroidism)
- how well ERLEADA® is working. Your healthcare professional may reduce your dose, temporarily stop, or permanently stop your treatment with ERLEADA® if you have certain side effects.

ERLEADA® can cause abnormal blood test results. Your healthcare professional may do blood tests to check for side effects.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ERLEADA®:

- Gemfibrozil, used to treat high fat levels in the blood
- Itraconazole, ketoconazole, used to treat fungal infections
- Midazolam, used to treat anxiety
- Omeprazole, used to treat gastroesophageal reflux disease (conditions where there is too much acid in the stomach)
- Warfarin, used to prevent blood clots
- Fexofenadine, used to treat allergies
- Rosuvastatin, used lower cholesterol levels
- Levothyroxine, used to treat thyroid conditions

You should not start; or stop; any other medications that you take before you talk with the healthcare professional who prescribed ERLEADA®.

How to take ERLEADA®:

- Take exactly as your healthcare professional tells you.
- Take at about the same time once a day.
- Swallow tablets whole.
- Take ERLEADA® with or without food.

If you have trouble swallowing the 60 mg tablets whole, use the method below:

For 60 mg tablets, mix with applesauce:

1. Place your entire dose of ERLEADA® 60 mg tablets in a container that contains 4 ounces (120 mL) of applesauce and stir the whole tablets. **Do not crush the tablets.**
2. Wait 15 minutes and stir the mixture again.
3. Wait another 15 minutes and stir the mixture again. Continue stirring until tablets are well mixed with no chunks remaining.
4. Swallow the mixture right away using a spoon.
5. Rinse the container with 2 ounces (60 mL) of water and drink the water mixture.
6. Repeat the rinse with 2 ounces (60 mL) of water one more time to make sure you take your full dose of ERLEADA®

Swallow all the applesauce and medicine mixture within 1 hour of preparation.

- **Do not** store ERLEADA® that is mixed in applesauce.

If you have trouble swallowing the 240 mg tablet whole, use one of the methods below:

For a 240 mg tablet, disperse in water and mix with one of the following non-fizzy drinks or soft foods: orange juice, green tea, applesauce, or drinkable yogurt. This may be done

as follows:

1. Place the whole ERLEADA[®] 240 mg tablet in a cup. **Do not crush or split the tablet.**
2. Add about 2 teaspoons (10 mL) of non-fizzy water to make sure that the tablet is completely in water.
3. Wait 2 minutes until the tablet is broken up and spread out (dispersed), then stir the mixture. Add in 6 teaspoons or 2 tablespoons (30 mL) of one of the following non-fizzy drinks or soft foods: orange juice, green tea, applesauce, or drinkable yogurt and stir the mixture.
4. Swallow the mixture right away.
5. Rinse the cup with enough water and drink it right away. This is to make sure you take your full dose of ERLEADA[®].

Do not save the medicine/food mixture for later use.

For a 240 mg tablet, give through a feeding tube:

ERLEADA[®] 240 mg tablet may also be given through certain feeding tubes. Ask your healthcare professional for specific instructions on how to properly take the tablet through a feeding tube.

Usual dose:

240 mg once a day. This is four 60 mg tablets **or** one 240 mg tablet.

- Your healthcare professional may change your ERLEADA[®] dose if needed.
- Do not stop taking your ERLEADA[®] without talking to your healthcare professional first.

You should start or continue a gonadotropin-releasing hormone (GnRH) analog therapy during your treatment with ERLEADA[®] unless you had surgical castration. This is a surgery to remove your testicles to lower the amount of testosterone in your body.

Overdose:

If you think you, or a person you are caring for, have taken too much ERLEADA[®], contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms

Missed dose:

If you miss a dose of ERLEADA[®], 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 extra tablets to make up the missed dose.

What are possible side effects from using ERLEADA[®]?

These are not all the possible side effects which you may feel when taking ERLEADA[®]. If you experience these or any side effects not listed here, contact your healthcare professional.

Side effects of ERLEADA[®] include:

- feeling tired
- high blood pressure
- skin rash
- itching
- diarrhea
- nausea
- decreased appetite
- changes in the way things taste
- low thyroid levels (hypothyroidism): (symptoms may include unexplained weight gain, dry skin, hair loss, hoarseness, constipation, fatigue, joint pain, muscle weakness, puffy face, feeling cold, heavier than normal or irregular menstrual periods)
- weight loss
- joint pain
- muscle spasm
- uncontrollable urge to move a part of the body, usually the leg (restless leg syndrome)
- falls
- hot flash
- swelling in hands, ankles, or feet

Tell your healthcare professional if you have any side effect that bothers you or that does not go away.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Fracture (broken bone)		✓	
COMMON			
Cardiac problems (including heart attack, heart disease, heart failure): pressure or pain in your chest or arms that may spread to neck, jaw or back, chest pain or discomfort or shortness of breath at rest or with activity, changes in heart rate, dizziness or lightheadedness, nausea			✓
Stroke or mini-stroke (bleeding or blood clot in the brain): Sudden numbness or weakness of your arm, leg or face, especially if only on one side of the body; sudden confusion, difficulty speaking or understanding others, sudden difficulty in walking			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
or loss of balance or coordination, suddenly feeling dizzy or sudden severe headache with no known cause.			
RARE			
Seizure (convulsion): muscle twitching, changes in emotions, confusion, loss of consciousness with uncontrollable shaking			✓
Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) (severe skin reactions) and DRUG Reaction with Eosinophilia and Systemic Symptoms (DRESS) (severe rash with fever and swollen glands): Redness, blistering and/or peeling of large areas of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands, rash all over body accompanied with fever, swollen glands and effects on blood cells and body parts.			✓
VERY RARE			
Interstitial lung disease (disorders that inflame or scar the lung tissue): Respiratory symptoms such as shortness of breath at rest or aggravated by effort, dry cough			✓
QT prolongation (an abnormal heart electrical signal): irregular heartbeat, dizziness, fainting, loss of consciousness		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store ERLEADA® at 15°C to 30°C, in the original package to protect from light and moisture.
- If your ERLEADA® 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.
- Keep out of reach and sight of children.
- Do not use ERLEADA® after the expiry date which is stated on the label. The expiry date refers to the last day of the month.

Proper disposal:

Medicines should not be discarded in the toilet or household garbage. Follow your local rules for discarding unused medicine. If you are not sure, ask your pharmacist how to throw away medicines you no longer need. This will help to protect the environment.

If you want more information about ERLEADA®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>);
- For questions, concerns, or the full Product Monograph go to: www.janssen.com/canada or contact the manufacturer, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

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