

What is ERLEADA[®]?

ERLEADA[®] (apalutamide) is a prescription medicine used for the treatment of prostate cancer:

- That has spread to other parts of the body and still responds to a medical or surgical treatment that lowers testosterone **OR**
- That has not spread to other parts of the body and no longer responds to a medical or surgical treatment that lowers testosterone

It is not known if ERLEADA[®] is safe and effective in females.

It is not known if ERLEADA[®] is safe and effective in children.

How should I take ERLEADA[®]?

The recommended dose of ERLEADA[®] is 240 mg (four 60 mg tablets) taken orally once daily.

- ✓ Take ERLEADA[®] exactly as your healthcare provider tells you
- ✓ Your healthcare provider may change your dose if needed
- ✓ Do not stop taking your prescribed dose of ERLEADA[®] without talking with your healthcare provider first
- ✓ Take your prescribed dose of ERLEADA[®] 1 time a day, at the same time each day
- ✓ Take ERLEADA[®] with or without food
- ✓ Swallow ERLEADA[®] tablets whole
- ✓ If you miss a dose of ERLEADA[®], take your normal dose as soon as possible on the same day. Return to your normal schedule on the following day. You should not take extra tablets to make up the missed dose
- ✓ You should start or continue a gonadotropin-releasing hormone (GnRH) analog therapy during your treatment with ERLEADA[®] unless you have had a surgery to lower the amount of testosterone in your body (surgical castration)
- ✓ If you take too much ERLEADA[®], call your healthcare provider or go to the nearest hospital emergency room



ONCE A DAY



ORALLY



WITH OR
WITHOUT FOOD

Doctor Discussion Guide

Seeing your doctor can sometimes feel intimidating. It doesn't have to be that way.

This Discussion Guide will help you have an open and honest conversation with your doctor.

1. How will you monitor my prostate cancer? What happens when my prostate cancer progresses? _____

2. How do you know if my prostate cancer has advanced? _____

3. What are my treatment options? Is ERLEADA[®] right for me? _____

4. Could ERLEADA[®] help slow my type of prostate cancer from advancing? _____

5. What information related to safety should I know about ERLEADA[®]? Can you explain the potential side effects? _____

6. If I am prescribed ERLEADA[®], how do I take it? How often do I take it? _____

IMPORTANT SAFETY INFORMATION

Before taking ERLEADA[®], tell your healthcare provider about all your medical conditions, including if you:

- Have a history of heart disease
- Have high blood pressure
- Have diabetes
- Have abnormal amounts of fat or cholesterol in your blood (dyslipidemia)
- Have a history of seizures, brain injury, stroke, or brain tumors
- Are pregnant or plan to become pregnant. ERLEADA[®] can cause harm to your unborn baby and loss of pregnancy (miscarriage)

Please see additional Important Safety Information on reverse side.

Please [click here](#) to see Important Product Information.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Before taking ERLEADA[®], tell your healthcare provider about all your medical conditions, including if you: (continued)

- Have a partner who is pregnant or may become pregnant
 - Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment and for 3 months after the last dose of ERLEADA[®]
 - Males should use a condom during sex with a pregnant female
 - Are breastfeeding or plan to breastfeed. It is not known if ERLEADA[®] passes into breast milk
- Talk with your healthcare provider if you have questions about birth control.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ERLEADA[®] can interact with many other medicines.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed ERLEADA[®].

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

What are the possible side effects of ERLEADA[®]?

ERLEADA[®] may cause serious side effects including:

- **Heart Disease.** Blockage of the arteries in the heart that can lead to death has happened in some people during treatment with ERLEADA[®]. Your healthcare provider will monitor you for signs and symptoms of heart problems during your treatment with ERLEADA[®]. Call your healthcare provider or go to the nearest emergency room right away if you get chest pain or discomfort at rest or with activity, or shortness of breath during your treatment with ERLEADA[®]
- **Fractures and Falls.** ERLEADA[®] treatment can cause bones and muscles to weaken and may increase your risk for falls and fractures. Falls and fractures have happened in people during treatment with ERLEADA[®]. Your healthcare provider will monitor your risks for falls and fractures during treatment with ERLEADA[®]
- **Seizure.** Treatment with ERLEADA[®] may increase your risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have a loss of consciousness or seizure. Your healthcare provider will stop ERLEADA[®] if you have a seizure during treatment

The most common side effects of ERLEADA[®] include:

- Feeling very tired
- Rash. Tell your healthcare provider if you get a rash
- Fall
- Hypertension
- Diarrhea
- Joint pain
- Decreased appetite
- Weight loss
- Hot flash
- Fracture

ERLEADA[®] may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility. **Do not** donate sperm during treatment with ERLEADA[®] and for 3 months after the last dose of ERLEADA[®].

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

These are not all the possible side effects of ERLEADA[®].

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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How should I store ERLEADA[®]?

- Store ERLEADA[®] at room temperature between 68°F to 77°F (20°C to 25°C).
- Store ERLEADA[®] in the original package.
- The bottle of ERLEADA[®] contains a desiccant packet to help keep your medicine dry (protect it from moisture). Do not throw away (discard) the desiccant.
- Protect ERLEADA[®] from light and moisture.

Keep ERLEADA[®] and all medicines out of the reach of children.

General information about the safe and effective use of ERLEADA[®].

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ERLEADA[®] for a condition for which it was not prescribed. Do not give ERLEADA[®] to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ERLEADA[®] that is written for health professionals.

What are the ingredients in ERLEADA[®]?

Active ingredient:

apalutamide

Inactive ingredients:

colloidal anhydrous silica, croscarmellose sodium, hydroxypropyl methylcellulose-acetate succinate, magnesium stearate, microcrystalline cellulose, and silicified microcrystalline cellulose. The film-coating contains iron oxide black, iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.



Manufactured by: Janssen Ortho LLC, Gurabo, PR 00778
Manufactured for: Janssen Products, LP, Horsham, PA 19044
For more information, go to www.erleada.com.

Please [click here](#) to see Important Product Information and discuss it with your doctor.

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