

**PATIENT INFORMATION**  
**ERLEADA™ (er lee'dah)**  
**(apalutamide)**  
**Tablets**

**What is ERLEADA?**

ERLEADA is a prescription medicine used to treat prostate cancer 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 or effective in children.

**Do not take ERLEADA if you:**

- are pregnant or may become pregnant. ERLEADA may harm your unborn baby.
- are female. ERLEADA is not for use in women.

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

- have a history of seizures, brain injury, stroke, or brain tumors
- have a partner who is pregnant or may become pregnant. Men who are sexually active with a pregnant woman must use a condom during and for 3 months after treatment with ERLEADA. If your sexual partner may become pregnant, an effective birth control (contraception) must be used during and for 3 months after treatment. 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.

**How should I take ERLEADA?**

- Take ERLEADA exactly as your healthcare provider tells you.
- 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.
- 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.
- 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 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.
- Your healthcare provider may do blood tests to check for side effects.

**What are the possible side effects of ERLEADA?**

**ERLEADA may cause serious side effects including:**

- **Falls and fractures.** 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. Falls were not caused by loss of consciousness (fainting) or seizures. Your healthcare provider will monitor your risks for falls and fractures during treatment with ERLEADA.
- **Seizure.** If you take ERLEADA, you may be at 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  | • weight loss                    |
| • high blood pressure | • joint pain                     |
| • rash                | • fall                           |
| • diarrhea            | • hot flash                      |
| • nausea              | • bone injury (fracture)         |
| • decreased appetite  | • swollen hands, ankles, or feet |

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.

**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

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For more information, call Janssen Products, LP at 1-800-526-7736 (1-800-JANSSEN) or go to [www.erleada.com](http://www.erleada.com).

This Patient Information has been approved by the U.S. Food and Drug Administration.

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