

ERLEADA® (apalutamide)

What are the possible side effects of ERLEADA?

ERLEADA may cause serious side effects, including¹:

Heart disease, stroke, or mini-stroke



Bleeding in the brain or blockage of the arteries in the heart or in parts of the brain have happened in some people during treatment with ERLEADA and can lead to death.

Your healthcare provider will monitor you for signs and symptoms of heart or brain problems during your treatment with ERLEADA. Call your healthcare provider or get medical help right away if you get any of the following symptoms:

- chest pain or discomfort at rest or with activity
- shortness of breath
- numbness or weakness of the face, arm, or leg, especially on one side of the body
- trouble talking or understanding
- trouble seeing in one or both eyes
- dizziness, loss of balance or coordination, or trouble walking

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 risk 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.

Severe skin reactions



Treatment with ERLEADA may cause severe skin reactions that can lead to death or be life-threatening.

Stop taking ERLEADA and tell your healthcare provider or get medical help right away if you develop any of these signs or symptoms of a severe skin reaction:

- severe rash or rash that continues to get worse
- fever or flu-like symptoms
- swollen lymph nodes
- blisters or sores in the mouth, throat, nose, eyes, or genital area
- blistering or peeling of the skin

Lung problems



Treatment with ERLEADA may cause inflammation of the lungs that can lead to death or be life-threatening.

Stop taking ERLEADA and tell your healthcare provider or get medical help right away if you develop any new or worsening symptoms of lung problems, including:

- shortness of breath
- cough
- fever

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What are the possible side effects of ERLEADA?

The most common side effects of ERLEADA include¹:



Feeling very tired



Joint pain



Rash. Tell your healthcare provider if you get a rash



Decreased appetite



Fall



Weight loss



High blood pressure



Hot flashes



Diarrhea



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.¹

Do not donate sperm during treatment with ERLEADA and for 3 months after the last dose of ERLEADA.¹



- Your healthcare provider may reduce your dose, temporarily stop, or permanently stop treatment with ERLEADA if you have certain side effects.¹
- Tell your healthcare provider if you have any side effect that bothers you or does not go away.¹
- These are not all the possible side effects of ERLEADA.¹
- Call your doctor for medical advice about side effects. You may report side effects to the Food and Drug Administration (FDA) at 1-800-FDA-1088.¹

This information is provided ONLY in response to your request and is not intended as medical advice, to promote the use of our product, or suggest using it in any manner other than as described in the PRESCRIBING INFORMATION. All decisions regarding your medical treatment should be made with your healthcare professional(s). Please contact your healthcare professional(s) to discuss the information in this response.

Please refer to the attached full PRESCRIBING INFORMATION, PATIENT INFORMATION, and the INSTRUCTIONS FOR USE for ERLEADA.¹

1. ERLEADA (apalutamide) [Prescribing Information]. Horsham, PA: Janssen Products, LP;

<https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ERLEADA-pi.pdf>.