

CARING FOR YOUR SKIN WHILE TAKING ERLEADA

Actor portrayals.

WHAT TO KNOW ABOUT POSSIBLE RASHES

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.

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 liver problems
- 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 full [Prescribing Information](#) for ERLEADA.

WHAT TO KNOW ABOUT SKIN RASH

In a clinical study, the efficacy and safety of ERLEADA + ADT (androgen deprivation therapy) was compared with placebo + ADT.* Rashes were usually mild to moderate and manageable with the healthcare provider's help.



Among those affected, rash symptoms generally began about **80 days** after starting ERLEADA. Most people who got a rash saw it disappear in about **80 days** (median time)



98% of people **continued** treatment with ERLEADA

95% of people **did not have** their dose reduced

*About the clinical study: TITAN was a randomized, double-blind, placebo-controlled, multinational, clinical study in which 1052 patients with mCSPC (metastatic castration-sensitive prostate cancer) received ERLEADA 240 mg once daily or a placebo.

IMPORTANT SAFETY INFORMATION (CONT'D)

Before taking ERLEADA, tell your healthcare provider about all your medical conditions, including if you: (cont'd)

- 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.

Talk with your healthcare provider if you have questions about birth control.

- are breastfeeding or plan to breastfeed. It is not known if ERLEADA passes into breast milk.

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.

Please see full [Prescribing Information](#) for ERLEADA.

IDENTIFYING A SKIN RASH

WHAT TO LOOK FOR

- Flat, discolored patch of skin
- Red spots
- Small, raised bumps
- Itchy welts
- Peeling or flaking skin

SKIN RASH CAN CAUSE

- Irritation and itchiness
- Burning
- Blistering
- Tightness
- Dryness

GRADE OF SKIN RASH

GRADE 1

Mild



Covers <10%
of the body

GRADE 2

Moderate



Covers 10% to 30%
of the body

GRADE 3

Severe



Covers >30%
of the body

TALK TO YOUR HEALTHCARE PROVIDER IF YOU NOTICE A RASH DEVELOPING. KEEP A NOTE OF:

- when the rash started
- where on the body it appears
- if it is spreading

This information will help your healthcare provider determine how to treat your rash.

CARING FOR SKIN RASH



During treatment with ERLEADA, your healthcare provider will closely monitor your skin rash symptoms and may recommend you:



Take prescribed pills and/or creams that your healthcare provider may order for you. These may be antihistamines, steroids, creams, or lotions to control and reduce rash



Clean affected skin with soap prescribed to you



Use sunblock (SPF 50) or protective clothing when outdoors



Shower or bathe in cool or lukewarm water, not hot water



Use alcohol-free and fragrance-free emollient cream for dry skin



Your healthcare provider may reduce your dose, or hold or stop treatment with ERLEADA.

YOU WERE because it treats your type of prostate cancer.
PRESCRIBED If a rash does occur, your care team is here to
ERLEADA help you manage it and stay on track.

IMPORTANT SAFETY INFORMATION (CONT'D)

How should I take ERLEADA?

- Take ERLEADA exactly as your healthcare provider tells you.
- 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. **Do not** crush or split the tablets.
- If you cannot swallow ERLEADA tablets whole or if you have a feeding tube, **see the “Instructions for Use” for detailed instructions** on how to prepare and take a dose of ERLEADA. ERLEADA comes in 2 different strengths (60 mg and 240 mg). Follow the instructions for your prescribed strength of ERLEADA.
- 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.

Please see full [Prescribing Information](#) for ERLEADA.

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of ERLEADA?

ERLEADA may cause serious side effects including:

- **Heart Disease, Stroke, or Mini-Stroke.** Bleeding in the brain or blockage of the arteries in the heart or in part 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:
 - 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 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.
- **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

FOR MORE INFORMATION ABOUT ERLEADA,
VISIT [ERLEADA.COM/WHY-ERLEADA](https://erleada.com/why-erleada).

ERLEADA HELPS YOU **TAKE THE LEAD**

VISIT [ERLEADA.COM](https://www.erleada.com)
TO LEARN MORE
ABOUT ERLEADA.

IMPORTANT SAFETY INFORMATION (CONT'D)

The most common side effects of ERLEADA include:

- feeling very tired
- joint pain
- rash. Tell your healthcare provider if you get a rash
- decreased appetite
- fall
- weight loss
- high blood pressure
- hot flash
- diarrhea
- fracture

Your healthcare provider may reduce your dose, temporarily stop, or permanently stop treatment with ERLEADA if you have certain side effects.

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.

Please see full [Prescribing Information](#) for ERLEADA.

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