

#### 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 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 throughout and on pages 10–11.

Please see full Prescribing Information for ERLEADA®.





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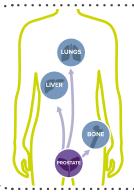
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## **KEEP BEING THEIR EVERYDAY HERO**

LEARN MORE ABOUT PATIENT SUPPORT

## ERLEADA® TREATS TWO TYPES OF PROSTATE CANCER

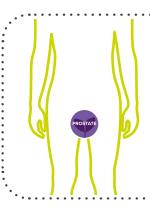
When it comes to prostate cancer treatment, it helps to understand your type of prostate cancer and how ERLEADA® can help. If your doctor has prescribed ERLEADA®, it's because you have one of the types of prostate cancer described below.



## **mCSPC**

## WHAT IS METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (mCSPC)?

Prostate cancer that **HAS SPREAD** to other parts of the body and **STILL RESPONDS** to medical or surgical treatment that lowers testosterone.



## **nmCRPC**

## WHAT IS NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (nmCRPC)?

Prostate cancer that **HAS NOT SPREAD** to other parts of the body and **NO LONGER** responds to medical or surgical treatment that lowers testosterone.

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

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

- 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®.



## **HOW ERLEADA® WORKS**

ERLEADA® + ADT work together to lower androgens that can help fuel prostate cancer



#### How androgens help fuel prostate cancer

- Androgens are male hormones, primarily testosterone, that are needed for the prostate to function normally
- However, when androgens attach to androgen receptors they can help fuel prostate cancer cell growth



#### The goal of ADT is to lower androgen levels

- Medical or surgical treatments that lower testosterone are also referred to as androgen deprivation therapy (ADT)
- ADT includes treatment to suppress or block the production or action of male hormones called androgens



#### ERLEADA® + ADT fight prostate cancer together

• ERLEADA® blocks androgens from attaching to receptors to help prevent cancer cells from growing

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

- 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.



## WHY ERLEADA® FOR mCSPC

Study design: ERLEADA® + ADT was compared with placebo + ADT in a clinical study of 1,052 men with mCSPC. 525 men received ERLEADA® + ADT and 527 men received placebo + ADT. See page 11 for the most common side effects of ERLEADA®.

#### **ERLEADA® WAS SHOWN TO HELP MEN LIVE LONGER**

**65%** of men were alive

In a clinical study, approximately 65% of men taking ERLEADA® + ADT were alive at 4 years vs 52% of men taking placebo + ADT.\*

\*Median (middle) data point has not been reached for ERLEADA®. Placebo + ADT median was 52 months. In an earlier analysis from the study, the reduction in the risk of death was 33%.

#### ERLEADA® HELPED MEN ACHIEVE A ZERO PSA LEVEL<sup>†</sup>



In a clinical study, ERLEADA® + ADT helped more than twice as many men achieve a zero PSA (prostate-specific antigen) level† vs placebo + ADT (68% vs 32%).‡

<sup>†</sup>Zero PSA level = <0.2 ng/mL. <sup>‡</sup>The relationship between ERLEADA® and PSA is not fully known.

#### **ERLEADA® MAY DELAY THE NEED FOR CHEMOTHERAPY**



In a clinical study, ERLEADA® + ADT reduced the risk of beginning chemotherapy by 61% vs placebo + ADT.§

§Median (middle) data point has not been reached.

See Most Common Side Effects on page 7.

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

**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.



## WHY ERLEADA® FOR nmCRPC

Study design: ERLEADA® + ADT was compared with placebo + ADT in a clinical study of 1,207 men with nmCRPC. 806 men received ERLEADA® + ADT and 401 men received placebo + ADT. See page 11 for the most common side effects of ERLEADA®.

ERLEADA® HELPED MEN WITH nmCRPC LIVE LONGER WITHOUT THE SPREAD OF PROSTATE CANCER



MEN LIVED OVER

## **2 YEARS LONGER**

without cancer spreading vs placebo + ADT

In a clinical study, ERLEADA® + ADT helped men live 2+ years longer without their cancer spreading to other parts or their body compared with men taking placebo + ADT (40.5 months vs 16.2 months).\*

\*Median (middle) follow-up was 20.3 months. In the primary analysis of the study, ERLEADA® + ADT reduced the risk of prostate cancer spreading or death by 72%.

ERLEADA® + ADT AND PSA RESPONSE<sup>†</sup>

AT 12 MONTHS

of men lowered PSA by 90%

Nearly  $\frac{2}{3}$  of men taking ERLEADA® + ADT lowered their PSA (prostate-specific antigen) by 90% at 12 months vs none taking placebo + ADT (61% vs 0%).

<sup>†</sup>PSA response to treatment with ERLEADA® is still being studied. The relationship between ERLEADA® and PSA is not fully known.

See Most Common Side Effects on page 7.

ERLEADA® MAY DELAY
THE NEED FOR
CHEMOTHERAPY

37%

lower risk of starting chemotherapy

In a clinical study, ERLEADA® + ADT reduced the risk of beginning chemotherapy by 37% vs placebo + ADT.<sup>‡</sup>

<sup>‡</sup>Median (middle) data point has not been reached.

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

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.



## **SIDE EFFECTS**

#### THE MOST COMMON SIDE EFFECTS OF ERLEADA® INCLUDE:



high blood pressure



diarrhea



hot flash



fracture



feeling very tired



decreased appetite



joint pain



fall



rash



weight loss

Your healthcare provider may reduce your dose or temporarily or permanently stop treatment with  ${\sf ERLEADA}^{\sf B}$  if you have certain side effects.



# ERLEADA® IS NOT CHEMOTHERAPY. IT'S TREATMENT YOU CAN TAKE AT HOME OR ON THE GO.



<sup>\*</sup> Take ERLEADA® as prescribed.

#### **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, see the INSTRUCTIONS FOR USE for detailed instructions on how to prepare and take a dose of ERLEADA® by mouth. 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.

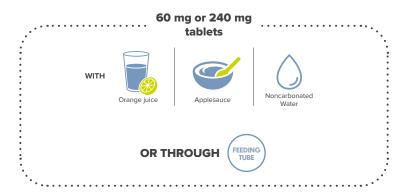


<sup>†</sup> Tablets shown are not actual size



# HAVE TROUBLE SWALLOWING TABLETS WHOLE OR USE A FEEDING TUBE?

#### THERE ARE ALTERNATE WAYS TO TAKE ERLEADA®



Visit <a href="https://www.ERLEADA.com/starting-erleada/">https://www.ERLEADA.com/starting-erleada/</a> to read or watch a video about alternative ways to prepare and take your prescribed dose of ERLEADA®.



## **IMPORTANT SAFETY INFORMATION (CONTINUED)**

#### How should I take ERLEADA®?

- Take your prescribed dose of ERLEADA®

  1 time a day, at the same time each day.
- Take ERLEADA® with or without food.
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- If you take too much ERLEADA®, call your healthcare provider or go to the nearest hospital emergency room.

## 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
  - o 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
  - o fever or flu-like symptoms
  - swollen lymph nodes
  - blisters or sores in the mouth, throat, nose, eyes, or genital area
  - o 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:
  - o shortness of breath
  - o cough
  - o fever



## **IMPORTANT SAFETY INFORMATION (CONTINUED)**

## 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.

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## Erleada with Me\_

## ERLEADA withMe SUPPORT IS WITH YOU

**ALONG THE WAY** 

Regardless of your insurance type, we can help you explore cost support options and provide comprehensive resources and education.

## SIGN UP FOR PERSONALIZED SUPPORT THROUGHOUT YOUR TREATMENT JOURNEY NOW

Visit <u>ERLEADAwithMe.com/signup</u> or call **833-565-9631**, Monday through Friday, 8:00 AM—8:00 PM ET.

The support and resources provided by ERLEADA withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

Please see Important Safety Information throughout and on pages 10–11, and full <u>Prescribing Information</u>.

Erleada (analutamida) 60 mg tablets

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