What is ERLEADA™ (apalutamide)?
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.

Please see the Important Safety Information on pages 13-15 and click here to see the ERLEADA™ Important Product Information.
You and your doctor have made an important decision in your fight against prostate cancer

Living with prostate cancer is challenging.

The treatment decision made by you and your doctor is an important step in continuing that fight. The fight against prostate cancer and starting a new treatment aren’t easy. Know that support is available to you along the way, beginning with this brochure.

Inside, you’ll find helpful and practical information for you and your loved ones. You’ll also discover useful tools and support services to help you get started and stay on track with your therapy.

So stay hopeful and determined. Now you have an option to help you keep fighting.
Men who are first diagnosed with prostate cancer that has not spread beyond the prostate have several treatment options. Individual condition and other factors are considered when choosing a treatment course. Options include:

**ACTIVE SURVEILLANCE**
A treatment plan that involves closely monitoring the cancer but not giving any treatment unless there are changes in test results that show the condition is getting worse.

Certain exams, such as digital rectal exam (DRE), prostate-specific antigen (PSA) blood tests, and sometimes biopsies, are done on a regular schedule.

**WATCHFUL WAITING**
This treatment plan includes monitoring the patient’s condition but usually involves fewer tests and not giving treatment unless symptoms appear or change.

**SURGERY**
Prostatectomy is a surgery to remove part or all of the prostate and some of the tissue around it.

**RADIATION THERAPY**
Radiation therapy uses high-energy rays or particles to kill cancer cells.

The majority of men respond to treatment at this stage and don’t need further treatment. For some men, the cancer may progress at some point.

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If the cancer continues to progress:
These men may receive hormone treatment called androgen deprivation therapy, or ADT. ADT is a treatment given to reduce or block the production and action of male hormones in the body called androgens, such as testosterone, which can help fuel prostate cancer cells.

There are different types of ADT. Two types that work by reducing testosterone are:

**Surgical**
- Orchiectomy (surgery to remove the testicles).

**Medical**
- There are several medical treatments that work to lower testosterone by reducing androgen production by the testicles or blocking the action of androgen in the body.
  - One type are medications called gonadotropin-releasing hormone (GnRH) analogs.
  - You may be familiar with Lupron Depot® (leuprolide acetate for depot suspension), a type of long-acting GnRH analog that is given as an injection.
  - Ask your doctor which type of ADT you have been receiving or have received.

NOTE: Lupron Depot® is provided as an example of ADT and is not an endorsement by Janssen Biotech, Inc.

Lupron Depot® (leuprolide acetate for depot suspension) is a registered trademark of AbbVie Inc.

ADT is often an effective treatment. After time, some prostate cancer can adapt and progress. When that happens, another treatment needs to be considered.
What is nmCRPC?

As discussed earlier, when prostate cancer progresses, men may receive medical or surgical treatments that lower testosterone, also referred to as androgen deprivation therapy (ADT).

ADT includes treatments to suppress or block the production or action of male hormones called androgens, including testosterone. While ADT is often effective, in certain men prostate cancer adapts and can progress.

Prostate-specific antigen ( PSA) is one of the ways your doctor may monitor your prostate cancer. Often, PSA levels rise, which could be one of the indicators that the cancer may be progressing. Bone and other types of scans are used to detect whether the cancer has spread to different parts of the body.

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 is called non-metastatic castration-resistant prostate cancer or nmCRPC.

- Scans showing no sign of cancer metastasizing (spreading)
- Have had a surgical treatment or are currently on a medical treatment that lowers testosterone
- Rising PSA levels while having low testosterone levels in the blood
What is metastasis?

Metastasis is the spread of cancer from the place where it first formed to another part of the body. Men with nmCRPC (non-metastatic castration-resistant prostate cancer) are at risk of developing metastasis.

The most common sites where prostate cancer can spread are bones, lymph nodes, liver, lungs, and brain.

Talk to your doctor to find out what metastasis could mean for you.
ERLEADA™ (apalutamide) + ADT helped certain patients live without metastasis 2 years longer than placebo + ADT

In a clinical trial, ERLEADA™ + ADT* delayed the spread of cancer to other parts of the body (metastasis) or death by 2 years (24.3 months).

**MEDIAN† MONTHS:** Median number of months living without metastasis.

<table>
<thead>
<tr>
<th>16.2 MONTHS</th>
<th>PLACEBO + ADT</th>
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<tbody>
<tr>
<td>40.5 MONTHS</td>
<td>ERLEADA™ + ADT</td>
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**24.3 ADDITIONAL MONTHS VS PLACEBO + ADT**

*ADT includes medical or surgical treatment that lowers testosterone.

†Median means that for 50% of the patients, living without metastasis was longer than 40.5 months, and for 50% of the patients, it was shorter than 40.5 months.

ERLEADA™ + ADT was compared to placebo + ADT in a clinical trial of more than 1200 men with non-metastatic castration-resistant prostate cancer (nmCRPC).

One group of men received ERLEADA™ (240 mg once daily) with ADT (had surgical treatment or were receiving treatment that lowers testosterone). The other group of men received a placebo‡ with ADT.

‡Pronounced “pluh-see-bow”: a pill that looks like “real” medicine but contains nothing to affect health.

Please see the Important Safety Information on pages 13-15 and click here to see the ERLEADA™ Important Product Information.
ERLEADA™ (apalutamide) + ADT helped certain patients live without metastasis 2 years longer than placebo + ADT

The clinical study also evaluated these additional measures:

**Time to Metastasis**
Length of time from when patient began study to when prostate cancer had spread to other parts of the body (based on imaging).

**Progression-Free Survival**
Length of time patients lived without their prostate cancer spreading to local or distant parts of the body or death.

**Overall Survival**
Length of time patients lived after starting treatment as part of the study.

**Important Safety Information**
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 partner may become pregnant, 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.

Please see the Important Safety Information on pages 13-15 and click here to see the ERLEADA™ Important Product Information.
How ERLEADA™ (apalutamide) + ADT works

Androgens can fuel cancer growth.
- 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 testosterone levels, but in certain cases, the cancer adapts.
- 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, primarily testosterone.
- While ADT is often effective, in certain men prostate cancer adapts to low levels of androgens.

ERLEADA™ works differently than ADT.
- ERLEADA™ blocks androgens from attaching to receptors to help prevent cancer cells from growing.
- ERLEADA™, an androgen receptor inhibitor, is the first prescription medicine approved for men with nmCRPC.

ERLEADA™ + ADT: working together to lower androgens that can help fuel the prostate cancer.

Please see the Important Safety Information on pages 13-15 and click here to see the ERLEADA™ Important Product Information.
How ERLEADA™ (apalutamide) + ADT works

Important Safety Information

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 the Important Safety Information on pages 13-15 and click here to see the ERLEADA™ Important Product Information.
Important Safety Information

Do not take ERLEADA™ (apalutamide) 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, 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.

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Click here to see the ERLEADA™ Important Product Information.
How should I take ERLEADA™ (apalutamide)?

- 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™.

(continued on next page)
Important Safety Information

Seizure. If you take ERLEADA™ (apalutamide), 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
- high blood pressure
- rash
- diarrhea
- nausea
- decreased appetite
- weight loss
- joint pain
- fall
- hot flash
- bone injury (fracture)
- 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.

Click here to see the ERLEADA™ Important Product Information.
How should I take ERLEADA™ (apalutamide)?

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.
- 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.
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- Your healthcare provider may do blood tests to check for side effects.

Please see the Important Safety Information on pages 13-15 and click here to see the ERLEADA™ Important Product Information.
Once you and your doctor have decided ERLEADA™ (apalutamide) is right for you

Your ERLEADA™ prescription will not be filled at your local retail pharmacy. If your doctor’s office has its own pharmacy, they can fill your prescription and you can pick it up there.

Otherwise, your doctor will send your prescription to a specialty pharmacy. A specialty pharmacy fills prescriptions for certain medicines that are not available at regular pharmacies.

Here’s what will happen:

1. Your doctor orders ERLEADA™
   - Your doctor’s office will let the specialty pharmacy know that you have been prescribed ERLEADA™

2. Wait for the specialty pharmacy’s call
   - The specialty pharmacy will call you to arrange delivery of your ERLEADA™. Make sure you return their call so that you receive your medicine on time. (You may want to ask your doctor’s office for the specialty pharmacy’s number so that you recognize it when they call.)
   - If you don’t hear from the specialty pharmacy in a few days, call your doctor’s office

3. Receive your ERLEADA™
   - Your ERLEADA™ will be delivered right to your home in about 2 weeks

Please see the Important Safety Information on pages 13-15 and click here to see the ERLEADA™ Important Product Information.
Once your doctor decides that ERLEADA™ (apalutamide) is right for you, Janssen CarePath can help you find the resources you may need to get started on your medication and stay on track.

Getting Started:
Janssen CarePath can review your health plan benefits and insurance coverage for ERLEADA™, and offer treatment education resources and access to nurses* who can answer your questions about ERLEADA™. We can work with your specialty pharmacy to process and deliver your medication to your home.

Staying on Track:
We understand how important it is for you to take your medication just as your doctor prescribed. Janssen CarePath provides ongoing support to help you stay on track with your ERLEADA™ treatment.

Paying for ERLEADA™:
We can identify cost support options that may help with managing your out-of-pocket costs—whether you have commercial or private insurance, government insurance such as Medicare or Medicaid, or have no insurance coverage.

*The nurse program is limited to education for patients about their Janssen therapy, its administration, and/or their disease, and is not intended to provide medical advice, replace a treatment plan from the patient’s doctor or nurse, or provide case management services.

Please see the Important Safety Information on pages 13-15 and click here to see the ERLEADA™ Important Product Information.
Janssen CarePath Savings Program:
If you use commercial or private health insurance:
The Janssen CarePath Savings Program provides eligible patients with instant savings on ERLEADA™ (apalutamide) medication costs.

PAY $10 A MONTH*

*Up to $15,000 maximum program benefit per calendar year or one-year supply, whichever comes first. Not valid for patients using Medicare, Medicaid, or any other government-funded programs. There is no income requirement. See full eligibility requirements at www.JanssenCarePath.com.

Personalized Account:
Sign up or log in to your personal Janssen CarePath Account at MyJanssenCarePath.com to check your insurance coverage; if eligible, enroll in the Janssen CarePath Savings Program; and sign up for nurse support or treatment reminders.

We’re just a phone call away!
Call a Janssen CarePath Care Coordinator at 1-833-ERLEADA (1-833-375-3232) Monday - Friday, 8AM - 8PM ET.

Please see the Important Safety Information on pages 13-15 and click here to see the ERLEADA™ Important Product Information.
Questions to ask your doctor

Always remember that your healthcare team should be your main source of treatment direction and information. You should have an open and honest conversation with them.

Here are some questions to help get you started:

Can you explain why my prostate cancer has advanced?

________________________________________________________________________

How will you monitor my prostate cancer?

________________________________________________________________________

Is ERLEADA™ (apalutamide) right for me?

________________________________________________________________________

Could ERLEADA™ delay my cancer from spreading to other parts of my body?

________________________________________________________________________

What Important Safety Information should I know about ERLEADA™? Can you explain the potential side effects?

________________________________________________________________________
We’re determined to fight together.

**TALK** to your doctor and healthcare team to be sure you receive clear instructions and information going forward.

If you have questions or concerns about your condition or treatment, don’t hesitate to:

**CALL** Janssen CarePath at **1-833-ERLEADA** (1-833-375-3232) for resources to help you stay on track. Monday - Friday, 8AM - 8PM ET.

**VISIT** [www.erleada.com](http://www.erleada.com) to find educational tools to help you stay on track.

**LEARN** about prostate cancer and how it can affect caregivers and families at [www.MyProstateCancerRoadmap.com](http://www.MyProstateCancerRoadmap.com).

**CONNECT** with organizations providing information and support at [www.cancer.com](http://www.cancer.com).