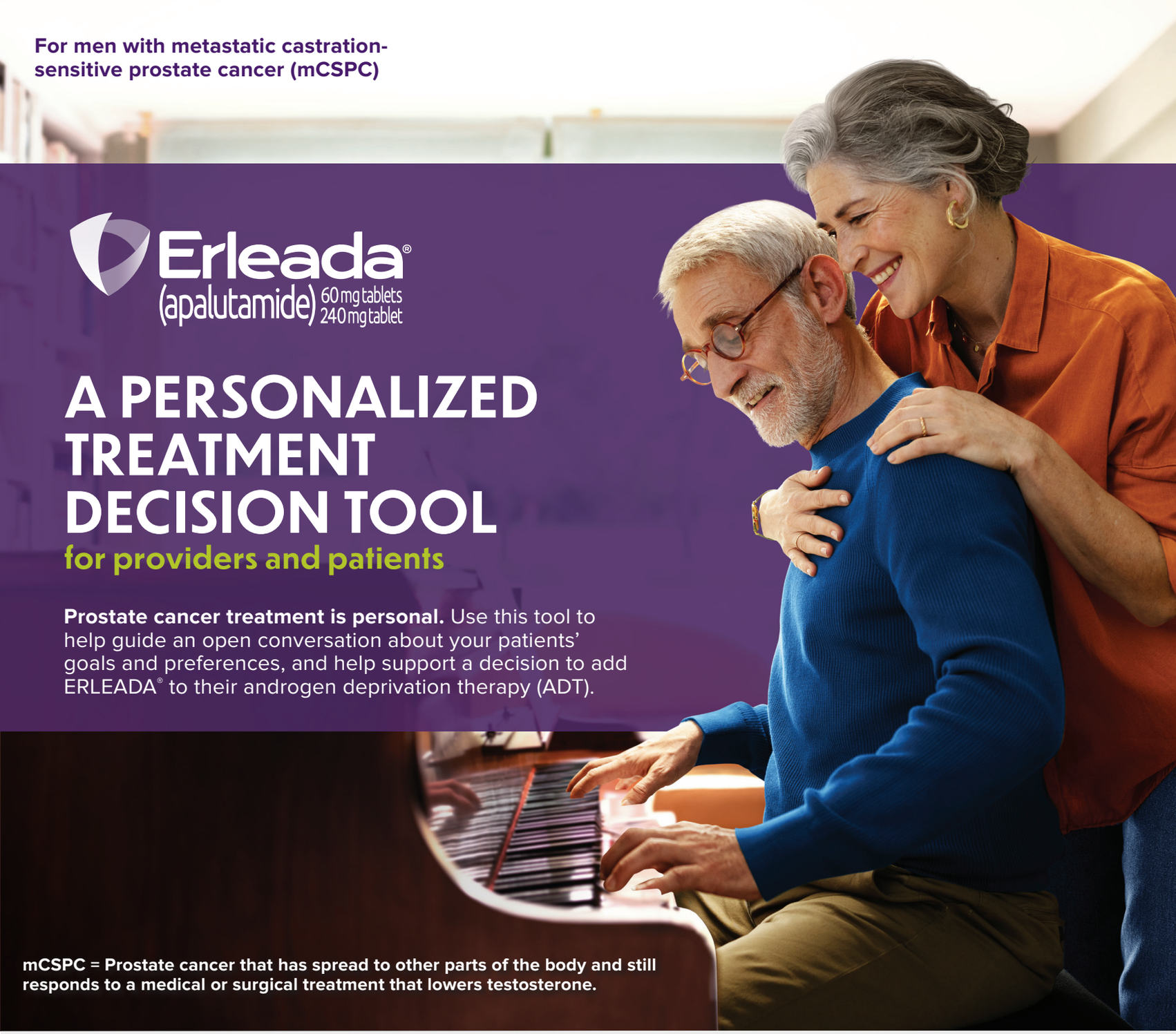
For men with metastatic castration-sensitive prostate cancer (mCSPC)

Erleada® (apalutamide) 60 mg tablets 240 mg tablet

A PERSONALIZED TREATMENT DECISION TOOL

for providers and patients

Prostate cancer treatment is personal. Use this tool to help guide an open conversation about your patients' goals and preferences, and help support a decision to add ERLEADA® to their androgen deprivation therapy (ADT).



mCSPC = Prostate cancer that has spread to other parts of the body and still responds to a medical or surgical treatment that lowers testosterone.

INDICATIONS

ERLEADA® (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with:

- Metastatic castration-sensitive prostate cancer (mCSPC)
- Non-metastatic castration-resistant prostate cancer (nmCRPC)

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Cerebrovascular and Ischemic Cardiovascular Events — In a randomized study (SPARTAN) of patients with nmCRPC, ischemic cardiovascular events occurred in 3.7% of patients treated with ERLEADA® and 2% of patients treated with placebo. In a randomized study (TITAN) in patients with mCSPC, ischemic cardiovascular events occurred in 4.4% of patients treated with ERLEADA® and 1.5% of patients treated with placebo. Across the SPARTAN and TITAN studies, 4 patients (0.3%) treated with ERLEADA® and 2 patients (0.2%) treated with placebo died from an ischemic cardiovascular event. Patients with history of unstable angina, myocardial infarction, congestive heart failure, stroke, or transient ischemic attack within 6 months of randomization were excluded from the SPARTAN and TITAN studies.

In the SPARTAN study, cerebrovascular events occurred in 2.5% of patients treated with ERLEADA® and 1% of patients treated with placebo. In the TITAN study, cerebrovascular events occurred in 1.9% of patients treated with ERLEADA® and 2.1% of patients treated with placebo. Across the SPARTAN and TITAN studies, 3 patients (0.2%) treated with ERLEADA® and 2 patients (0.2%) treated with placebo died from a cerebrovascular event.

Cerebrovascular and ischemic cardiovascular events, including events leading to death, occurred in patients receiving ERLEADA®. Monitor for signs and symptoms of ischemic heart disease and cerebrovascular disorders. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Consider discontinuation of ERLEADA® for Grade 3 and 4 events.

Please see additional Important Safety Information throughout this brochure.

HOW TO USE THIS GUIDE WITH YOUR PATIENT

Erleada® (apalutamide) 60 mg tablets 240 mg tablet

1 Use the questions below to discuss your patient's priorities when it comes to prostate cancer treatment

2 Give the tear sheet on the following pages to your patient so they can ask questions and take notes

3 Move on to the goals map to explore adding ERLEADA® to their androgen deprivation therapy (ADT)

ASSESS TREATMENT GOALS

- What is important to you in prostate cancer treatment options?
- In addition to living longer, what are your treatment goals?
- How important is it to lower your prostate-specific antigen (PSA) quickly and keep it low?

DISCUSS SPECIFIC MEDICATION CONCERNS

- Are you able to easily swallow tablets whole?
- Are side effects a concern for you (eg, fatigue, pain, or something else)?

EVALUATE EMOTIONAL WELL-BEING AND KNOWLEDGE

- How do you feel about your current treatment regimen?
- Do you understand why your provider might want to prescribe a treatment in addition to ADT?

ASSESS NEED FOR COST AND MEDICATION SUPPORT

- Do you need help understanding how much you may pay for your medication?
- What would having personal one-on-one phone support mean to you?

OPEN THE PAGE TO FIND MORE INFORMATION ABOUT ERLEADA®.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Fractures — In a randomized study (SPARTAN) of patients with nmCRPC, fractures occurred in 12% of patients treated with ERLEADA® and in 7% of patients treated with placebo. In a randomized study (TITAN) of patients with mCSPC, fractures occurred in 9% of patients treated with ERLEADA® and in 6% of patients treated with placebo. Evaluate patients for fracture risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone-targeted agents.

Falls — In a randomized study (SPARTAN), falls occurred in 16% of patients treated with ERLEADA® compared with 9% of patients treated with placebo. Falls were not associated with loss of consciousness or seizure. Falls occurred in patients receiving ERLEADA® with increased frequency in the elderly. Evaluate patients for fall risk.

Seizure — In 2 randomized studies (SPARTAN and TITAN), 5 patients (0.4%) treated with ERLEADA® and 1 patient treated with placebo (0.1%) experienced a seizure. Permanently discontinue ERLEADA® in patients who develop a seizure during treatment. It is unknown whether anti-epileptic medications will prevent seizures with ERLEADA®. Advise patients of the risk of developing a seizure while receiving ERLEADA® and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others.

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GET TO KNOW ERLEADA® (apalutamide)

A longer life may still be possible for your patient with mCSPC

IN THE TITAN STUDY (DUAL PRIMARY ENDPOINTS):

35%

Reduction in the risk of death compared with ADT alone[1,2]

Median OS: NR vs 52.2 months; HR=0.65; 95% CI: 0.53, 0.79; Median follow-up: 44.0 months. The TITAN primary analysis results: Median OS: NE vs NE; HR=0.67; 95% CI: 0.51, 0.89, *P*=0.0053. Median follow-up time was 22.7 months.

52%

Reduction in the risk of radiographic progression or death compared with ADT alone[1]

Median rPFS NE vs 22.1 months; HR=0.48; 95% CI: 0.39, 0.60; *P*<0.0001; Median follow-up time for primary analysis: 22.7 months.

Study Design: TITAN was a phase 3, multicenter, randomized, double-blind, placebo-controlled trial of patients with mCSPC (N=1052). Patients had newly diagnosed mCSPC or relapsed metastatic disease after an initial diagnosis of localized disease. Patients with visceral (ie, liver or lung) metastases as the only sites of metastases were excluded. Patients were randomized 1:1 to receive ERLEADA® 240 mg orally once daily or placebo orally once daily. All patients in the TITAN trial received a concomitant GnRH analog or had a prior bilateral orchiectomy. The dual primary endpoints were overall survival and rPFS.

UNDETECTABLE PSA LEVELS[1]

More than twice as many patients who received ERLEADA® + ADT achieved undetectable PSA compared with ADT alone (68% vs 32%).

Undetectable PSA was defined as ≤0.2 ng/mL. The exposure-response relationship and time course of pharmacodynamic response for the safety and effectiveness of apalutamide have not been fully characterized.[1]

MAINTAINED HEALTH-RELATED QUALITY OF LIFE (HRQoL)

HRQoL was maintained with ERLEADA® + ADT after a median follow-up of 44.0 months. Analysis of change from baseline in the FACT-P total score showed no substantial between-group differences.*

The HRQoL analyses (pre-specified exploratory endpoint) are not in the ERLEADA® Prescribing Information. HRQoL should be viewed in the context of patient management and the overall physical condition and clinical course of the patient.

ESTABLISHED SAFETY PROFILE

The most common adverse reactions (≥10%) that occurred more frequently in the ERLEADA®-treated patients (≥2% over placebo) from the randomized placebo-controlled clinical trials (TITAN and SPARTAN) were fatigue, arthralgia, rash, decreased appetite, fall, weight decreased, hypertension, hot flush, diarrhea, and fracture.

In the TITAN study, serious adverse reactions occurred in 20% of patients in the ERLEADA® + ADT arm and 20% in the placebo + ADT arm. The discontinuation rate due to adverse reactions was 8% in the ERLEADA® + ADT arm.[1]

VISIT ERLEADAHCP.COM/EFFICACY TO LEARN MORE

*The FACT-P patient-reported outcome questionnaire was used to assess prostate cancer symptoms, pain-related symptoms, and overall HRQoL in the TITAN study. The FACT-P is a 39-item questionnaire developed and validated specially in patients with prostate cancer.

ADT = androgen deprivation therapy; CI = confidence interval; FACT-P = Functional Assessment of Cancer Therapy-Prostate; GnRH = gonadotropin-releasing hormone; HR = hazard ratio; NE = not estimable; NR = not reached; OS = overall survival; PSA = prostate-specific antigen; rPFS = radiographic progression-free survival; SPARTAN = Selective Prostate Androgen Receptor Targeting with ARN-509; TITAN = Targeted Investigational Treatment Analysis of Novel Anti-androgen.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Severe Cutaneous Adverse Reactions — Fatal and life-threatening cases of severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) occurred in patients receiving ERLEADA®.

Please see additional Important Safety Information throughout this brochure.

PROSTATE CANCER TREATMENT OPTIONS

ERLEADA® is the only novel‡ androgen receptor inhibitor (ARI) available in just one daily 240 mg tablet for treatment of mCSPC§,1,3-4

FDA-approved androgen receptor inhibitors for the treatment of mCSPC¶

	Tablets per Week	No Chemotherapy	Alternate Methods of Administration	Can Be Taken With or Without Food
ERLEADA® (apalutamide) 240 mg tablet/ 60 mg tablets	One 240 mg tablet QD OR Four 60 mg tablets QD	✓	✓#	✓
Nubeqa® (darolutamide) 300 mg tablets	Two 300 mg tablets BID	Administered in combination with docetaxel	No alternate methods	With food
Xtandi® (enzalutamide) 40 mg tablets/ 80 mg tablets	Four 40 mg tablets QD OR Two 80 mg tablets QD	✓	No alternate methods	✓

COMPREHENSIVE PATIENT COVERAGE

ERLEADA® is covered for *93%* of commercial patients and **97%** of Medicare Part D patients.[5]

‡ERLEADA® is a second-generation ARI.

§Patients receiving these ARI therapies should also receive a GnRH analog concurrently or should have had bilateral orchiectomy.

¶Product comparisons with regard to efficacy and safety cannot be made in the absence of head-to-head clinical studies. This presentation is not intended to compare the relative efficacy or safety of the treatments. Please refer to the full Prescribing Information of each agent for dosage and administration.

#Alternate methods of administration in patients who have difficulty swallowing tablets whole or who have a feeding tube. For detailed instructions on administration, please see the full ERLEADA® Prescribing Information.

References:
1. ERLEADA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Chi KN, Chowdhury S, Bjartell A, et al. Apalutamide in patients with metastatic castration-sensitive prostate cancer: final survival analysis of the randomized, double-blind, phase III TITAN study. *J Clin Oncol*. 2021;39(20):2294-2303. **3.** NUBEQA® [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc. **4.** XTANDI® [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc. **5.** Managed Markets Insights and Technology (MMIT), February 2022.

ARI = androgen receptor inhibitor; BID = twice a day; GnRH = gonadotropin-releasing hormone; QD = once a day.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Monitor patients for the development of SCARs. Advise patients of the signs and symptoms of SCARs (eg, a prodrome of fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy). If a SCAR is suspected, interrupt ERLEADA® until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended. If a SCAR is confirmed, or for other Grade 4 skin reactions, permanently discontinue ERLEADA® *[see Dosage and Administration (2.2)]*.

Interstitial Lung Disease (ILD)/Pneumonitis — Fatal and life-threatening interstitial lung disease (ILD) or pneumonitis can occur in patients treated with ERLEADA®.
Post-marketing cases of ILD/pneumonitis, including fatal cases, occurred in patients treated with ERLEADA®. Across clinical trials (TITAN and SPARTAN, n=1327), 0.8% of patients treated with ERLEADA® experienced ILD/pneumonitis, including 0.2% who experienced Grade 3 events [*see Adverse Reactions (6.1, 6.2)*].
Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold ERLEADA® if ILD/pneumonitis is suspected. Permanently discontinue ERLEADA® in patients with severe ILD/pneumonitis or if no other potential causes of ILD/pneumonitis are identified [*see Dosage and Administration (2.2)*].
Embryo-Fetal Toxicity — The safety and efficacy of ERLEADA® have not been established in females. Based on findings from animals and its mechanism of action, ERLEADA® can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of ERLEADA® *[see Use in Specific Populations (8.1, 8.3)]*.

ADVERSE REACTIONS

The most common adverse reactions (≥10%) that occurred more frequently in the ERLEADA®-treated patients (≥2% over placebo) from the randomized placebo-controlled clinical trials (TITAN and SPARTAN) were fatigue, arthralgia, rash, decreased appetite, fall, weight decreased, hypertension, hot flush, diarrhea, and fracture.

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Laboratory Abnormalities — All Grades (Grade 3-4)

- **Hematology —** In the TITAN study: white blood cell decreased ERLEADA® 27% (0.4%), placebo 19% (0.6%). In the SPARTAN study: anemia ERLEADA® 70% (0.4%), placebo 64% (0.5%); leukopenia ERLEADA® 47% (0.3%), placebo 29% (0%); lymphopenia ERLEADA® 41% (1.8%), placebo 21% (1.6%)
- **Chemistry —** In the TITAN study: hypertriglyceridemia ERLEADA® 17% (2.5%), placebo 12% (2.3%). In the SPARTAN study: hypercholesterolemia ERLEADA® 76% (0.1%), placebo 46% (0%); hyperglycemia ERLEADA® 70% (2%), placebo 59% (1.0%); hypertriglyceridemia ERLEADA® 67% (1.6%), placebo 49% (0.8%); hyperkalemia ERLEADA® 32% (1.9%), placebo 22% (0.5%)

Rash — In 2 randomized studies (SPARTAN and TITAN), rash was most commonly described as macular or maculopapular. Adverse reactions of rash were 26% with ERLEADA® vs 8% with placebo. Grade 3 rashes (defined as covering >30% body surface area [BSA]) were reported with ERLEADA® treatment (6%) vs placebo (0.5%).

The onset of rash occurred at a median of 83 days. Rash resolved in 78% of patients within a median of 78 days from onset of rash. Rash was commonly managed with oral antihistamines and topical corticosteroids, and 19% of patients received systemic corticosteroids. Dose reduction or dose interruption occurred in 14% and 28% of patients, respectively. Of the patients who had dose interruption, 59% experienced recurrence of rash upon reintroduction of ERLEADA®.

Hypothyroidism — In 2 randomized studies (SPARTAN and TITAN), hypothyroidism was reported for 8% of patients treated with ERLEADA® and 1.5% of patients treated with placebo based on assessments of thyroid-stimulating hormone (TSH) every 4 months. Elevated TSH occurred in 25% of patients treated with ERLEADA® and 7% of patients treated with placebo. The median onset was at the first scheduled assessment. There were no Grade 3 or 4 adverse reactions. Thyroid replacement therapy, when clinically indicated, should be initiated or dose adjusted.

DRUG INTERACTIONS

Effect of Other Drugs on ERLEADA® — Co-administration of a strong CYP2C8 or CYP3A4 inhibitor is predicted to increase the steady-state exposure of the active moieties. No initial dose adjustment is necessary; however, reduce the ERLEADA® dose based on tolerability *[see Dosage and Administration (2.2)]*.

Effect of ERLEADA® on Other Drugs

CYP3A4, CYP2C9, CYP2C19, and UGT Substrates — ERLEADA® is a strong inducer of CYP3A4 and CYP2C19, and a weak inducer of CYP2C9 in humans. Concomitant use of ERLEADA® with medications that are primarily metabolized by CYP3A4, CYP2C19, or CYP2C9 can result in lower exposure to these medications. Substitution for these medications is recommended when possible or evaluate for loss of activity if medication is continued. Concomitant administration of ERLEADA® with medications that are substrates of UDP-glucuronosyl transferase (UGT) can result in decreased exposure. Use caution if substrates of UGT must be co-administered with ERLEADA® and evaluate for loss of activity.

P-gp, BCRP, or OATP1B1 Substrates — Apalutamide is a weak inducer of P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), and organic anion transporting polypeptide 1B1 (OATP1B1) clinically. Concomitant use of ERLEADA® with medications that are substrates of P-gp, BCRP, or OATP1B1 can result in lower exposure of these medications. Use caution if substrates of P-gp, BCRP, or OATP1B1 must be co-administered with ERLEADA® and evaluate for loss of activity if medication is continued.

Please see full Prescribing Information for ERLEADA®.

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PROSTATE CANCER TREATMENT IS PERSONAL

Erleada® (apalutamide) 60 mg tablets 240 mg tablet

WHAT TO EXPECT FROM YOUR TREATMENT DISCUSSION:

1. Your healthcare provider will start by asking you some questions
2. Be sure to ask about anything that is unclear; some helpful examples are listed below
3. Use the goals map on the back to learn why ERLEADA® may be an option to add to your androgen deprivation therapy (ADT)

- What are the treatment options that may help me reach my goals?
- Are there any nonchemotherapy options?
- What are my options if I have trouble swallowing tablets whole?
- Will adding a treatment to ADT help me live longer?
- What are the treatment options that may help lower my PSA (prostate-specific antigen)?
- What are the side effects of adding a treatment to ADT?
- Are there resources to help me understand insurance and how much I may pay for medication?
- What will my quality of life be if we add a treatment to ADT?

OPEN TO LEARN MORE ABOUT SAVINGS AND SUPPORT OFFERINGS FOR ERLEADA®

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.

Please see Important Safety Information throughout this brochure.

ERLEADA® & YOU

I don't want to be on chemotherapy or have to visit an office for treatment

ERLEADA® IS NOT CHEMOTHERAPY
Take it from home or on the go. No need for chemotherapy while taking. May also delay the start of chemotherapy

I want a treatment option that works with ADT to help me live longer

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

I have difficulty swallowing pills whole, or I have a feeding tube

FLEXIBLE ADMINISTRATION
ERLEADA® can be taken with or without food and has alternate methods for people with difficulty swallowing whole tablets or who have a feeding tube

I am concerned about side effects like feeling very tired

MOST COMMON SIDE EFFECTS
Feeling very tired, joint pain, rash, decreased appetite, fall, weight loss, high blood pressure, hot flash, diarrhea, and fracture

It's hard for me to keep track of all the pills I'm taking

ONE PILL, ONCE A DAY
ERLEADA® is available in one 240 mg pill taken once a day

I want a treatment option that can also help lower my PSA

ERLEADA® HELPS LOWER PSA
ERLEADA® + ADT lowered PSA in more than 2X as many men vs placebo + ADT (68% vs 32%). The relationship between ERLEADA® and PSA is not fully known

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).

PERSONALIZED SUPPORT. FROM PEOPLE WHO CARE.

Erleada® (apalutamide) 60 mg tablets 240 mg tablet

Starting and staying on track with a new medication can feel overwhelming. A Care Navigator is here to help with free personalized 1-on-1 support over the phone, available in both English and Spanish. When you sign up, your dedicated Care Navigator can help with:

- Paying for your medication
- Learning about your treatment
- Empowering support

Data rates may apply.

CLICK HERE OR SCAN THE CODE TO LEARN MORE AND SIGN UP

You can also sign up by calling 833-JNJ-wMe1 (833-565-9631), Monday through Friday from 8:00 AM to 8:00 PM ET.

NOTES

IMPORTANT SAFETY INFORMATION (CONTINUED)

- have a partner who is pregnant or may become pregnant.
  - o 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®.
  - o 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.

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- 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).
- 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.

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.
- 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.

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

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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