

DOCTOR DISCUSSION GUIDE



What is XTANDI?

XTANDI is a prescription medicine used to treat men with prostate cancer that:

- no longer responds to a hormone therapy or surgical treatment to lower testosterone OR
- has spread to other parts of the body and responds to a hormone therapy or surgical treatment to lower testosterone
 OR
- has not spread to other parts of the body and responds to a hormone therapy or surgical treatment to lower testosterone, and who are at high risk of cancer spreading to other parts of the body

It is not known if XTANDI is safe and effective in females or children.

Select Safety Information

XTANDI may cause serious side effects including seizure. If you take XTANDI, you may be at risk of having a seizure. Avoid activities where a sudden loss of consciousness could seriously harm you or someone else. Tell your doctor right away if you lose consciousness or have a seizure.

Questions for your next appointment

Your health is a team effort, and you can be a key player. We've created this guide full of questions to ask your doctor about advanced prostate cancer and XTANDI.



Self-assessment

In addition to living longer, what are your treatment goals? For many people with advanced prostate cancer, these can include:

- Delaying cancer progression
- Understanding test results, including PSA
- Delaying the start of chemotherapy
- $\boldsymbol{\cdot}$ Medication that only has to be taken once a day
- Understanding treatment options
- Understanding the side effects

Other: ____



Start a conversation about XTANDI

- 1. Can XTANDI help patients:
 - · Live longer?
 - · Delay the progression or spread of cancer?
 - Lower the chances of having to start a new chemotherapy regimen?
- 2. When is the right time to start XTANDI?
 - Are there benefits of starting XTANDI now?
- 3. What are the potential side effects?
- 4. Will my insurance cover XTANDI?
 - Can I get assistance paying for XTANDI?
- 5. How do I take XTANDI? How often do I need to take XTANDI?
 - Do I need to take XTANDI with food?
- 6. How extensively has XTANDI been studied, tested, and used in patients?

Important Safety Information

What should I tell my doctor before taking XTANDI?

Tell your doctor about all your medical conditions, including if you:

- · Have a history of seizures, brain injury, stroke, or brain tumors.
- Have a history of heart disease, have high blood pressure, or have abnormal amounts of fat or cholesterol in your blood (dyslipidemia).
- Are pregnant or plan to become pregnant. XTANDI 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 with XTANDI and for 3 months after the last dose.
 - Males must use a condom during sex with a pregnant female.
- Are breastfeeding or plan to breastfeed. It is not known if XTANDI passes into your breast milk.
- **Take other medicines.** XTANDI may affect the way other medicines work, and other medicines may affect how XTANDI works. These include prescription and over-the-counter medicines, vitamins, and herbal supplements. Do not start or stop any medicine without talking to your doctor.

How should I take XTANDI?

Xastellas

- Take XTANDI exactly as your doctor tells you. Take your prescribed dose once a day, at the same time each day. XTANDI can be taken with or without food. Swallow XTANDI capsules or tablets whole with enough water to make sure that you can swallow all of the medicine successfully. **Do not** chew, dissolve, or open the capsules. **Do not** cut, crush or chew the tablets. Your doctor may change your dose if needed. Your doctor may also change your pill size or stop treatment if you have swallowing problems.
- Do not change or stop taking your prescribed dose of XTANDI without talking with your doctor first.
- If you are receiving gonadotropin-releasing hormone (GnRH) therapy, you should continue with this treatment while taking XTANDI unless you have had surgery to lower the amount of testosterone in your body (surgical castration).
- If you miss a dose of XTANDI: Take your prescribed dose as soon as you remember that day. If you miss your daily dose, take your prescribed dose at your regular time the next day. Do not take more than your prescribed dose of XTANDI each day.
- If you take too much XTANDI: Call your doctor or go to the nearest emergency room right away. You may have an increased risk of seizure if you take too much XTANDI.

What are the possible side effects of XTANDI?

XTANDI may cause serious side effects including:

- **Seizure.** If you take XTANDI, you may be at risk of having a seizure. Avoid activities where a sudden loss of consciousness could seriously harm you or someone else. Tell your doctor right away if you lose consciousness or have a seizure.
- **Posterior Reversible Encephalopathy Syndrome (PRES).** If you take XTANDI you may be at risk of developing a condition involving the brain called PRES. Tell your doctor right away if you have a seizure or quickly worsening symptoms such as headache, decreased alertness, confusion, reduced eyesight, blurred vision or other visual problems. Your doctor will do a test to check for PRES.
- Allergic Reactions. Allergic reactions have happened in people who take XTANDI. Stop taking XTANDI and get medical help right away if you develop swelling of the face, tongue, lip or throat.
- **Heart Disease.** Blockage of the arteries in the heart (ischemic heart disease) that can lead to death has happened in some people during treatment with XTANDI. Your doctor will monitor you for signs and symptoms of heart problems during your treatment. Call your doctor or go to the emergency room right away if you get chest pain or discomfort at rest or with activity or shortness of breath during your treatment with XTANDI.
- Falls and Bone Fractures. XTANDI treatment may increase your risk for falls and bone fractures. Falls were not caused by loss of consciousness or seizures. Your doctor will monitor your risks for falls and bone fractures during treatment with XTANDI.
- **Swallowing Problems or Choking.** Severe swallowing problems or choking, including life-threatening problems or death can happen in people during treatment with XTANDI, because of the size of the XTANDI capsules and tablets. Swallow each XTANDI capsule or tablet whole with enough water to make sure that you can swallow all of the medicine successfully.

Your doctor will stop treatment with XTANDI if you have serious side effects.

The most common side effects of XTANDI include:

- High blood pressure
- Feeling more tired than usual
- Hot flashes
- Falls

· Bleeding problems

Constipation

Diarrhea

- Bone fracturesHeadache
- Decreased appetite

Muscle and joint pain

XTANDI may cause fertility problems in males, which may affect the ability to father children. Talk to your doctor if you have concerns about fertility.

These are not all the possible side effects of XTANDI. For more information, talk to your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or <u>www.fda.gov/medwatch</u>.

For further information, please talk to your doctor and click here for <u>Patient Information</u> and <u>Full Prescribing Information</u> for XTANDI.



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