

Understand medical terminology

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.

CLINICAL GLOSSARY

Use this glossary of clinical terms to help you better understand medical terminology and take an active role in your health.

Advanced prostate cancer

Prostate cancer that has progressed and that may be able to be treated, but is unlikely to be cured.

Androgen

A group of sex hormones, primarily testosterone, that play a role in the reproductive system, help maintain sexual desire and function, and more.

Androgen deprivation therapy (ADT)

ADT reduces the amount of testosterone the body makes.

Androgen receptor inhibitor (ARI)

ARIs are a type of novel hormone therapy (NHT). ARIs decrease how often androgens like testosterone connect with an androgen receptor, and thereby may slow the growth of prostate cancer tumors and cells.

Biopsy

The only test that can confirm prostate cancer, this procedure involves removing cells or a small piece of tissue from your body and testing it for cancerous cells.

Bone scan

A procedure to check for abnormal areas or damage in the bones.

Castration-resistant prostate cancer (CRPC)

Also called “hormone-resistant prostate cancer,” this type of prostate cancer no longer responds to hormone therapy or surgical treatment to lower testosterone.

Castration-sensitive prostate cancer (CSPC)

Also called “hormone-sensitive prostate cancer,” this type of prostate cancer responds to hormone therapy or surgical treatment to lower testosterone.

Computed tomography (CT) scan

A procedure that uses a computer linked to an X-ray machine to make a series of detailed pictures of areas inside the body. The pictures are taken from different angles and are used to create three-dimensional (3-D) views of tissues and organs.

De novo cancer

A term that describes the first occurrence of cancer in the body.

Gleason score

A grading system used by healthcare providers to assess a prostate cancer’s aggressiveness. It is based on how cells from the tumor look under a microscope—more aggressive tumor cells look less like normal tissue. The higher the Gleason score, the more aggressive your cancer may be. Doctors use the Gleason score to help choose the most appropriate treatments.

Hormone

One of many substances made by glands in the body. Hormones circulate in the bloodstream and control the actions of certain cells or organs.

Imaging

A scan that helps doctors monitor a disease or decide on treatment. Common imaging scans used for cancer include MRI, PSMA PET, and PET/CT scans.

Luteinizing hormone-releasing hormone (LHRH) therapy

A form of ADT, LHRH agonists prevent the release of LHRH, whereas LHRH antagonists block the pituitary gland from making LHRH. Lack of LHRH causes the testicles to stop making testosterone.

Magnetic resonance imaging (MRI) scan

A procedure in which radio waves and a powerful magnet linked to a computer are used to show the difference between normal and diseased tissue; especially useful for imaging the brain, spine, bones, joints, and soft tissues.

Median

A statistical term meaning the middle value in a set of numbers.

Medication holiday

A medication holiday may be recommended by your doctor. This means you may take a break from your treatment. The length of your break will be determined by your doctor. Take your medication as prescribed by your doctor.

Metastatic

A term describing cancer that has spread from the place where it started to other places in the body, such as nearby or distant bones, tissues, or other organs.

Novel hormone therapy (NHT)

NHTs (which include ARIs) are a type of hormone therapy used to treat advanced prostate cancer. They work by inhibiting the production of androgens or by inhibiting the connection of androgens to androgen receptors within the body, helping to slow cancer cell growth.

Overall survival

The length of time a patient is alive after the start of treatment.

Progression

The course of a disease as it gets worse or spreads in the body.

Prostate-specific antigen (PSA)

A protein made inside the prostate. Its job is to help semen transport sperm. An unusually high amount of PSA in the blood may be a sign of prostate cancer.

Testosterone

A hormone made in the testes, required for development of male sex characteristics, such as muscle growth and facial hair.

Tumor

An abnormal mass of tissue that results when cells grow or divide more than they should or live longer than they should. Tumors can be benign (noncancerous) or malignant (cancerous).

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?

- **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:

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|---------------------------------|-----------------------|
| • Muscle and joint pain | • High blood pressure |
| • Feeling more tired than usual | • Bleeding problems |
| • Hot flashes | • Falls |
| • Constipation | • Bone fractures |
| • Decreased appetite | • Headache |
| • Diarrhea | |

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 www.fda.gov/medwatch.

For further information, please talk to your doctor and click here for [Patient Information and Full Prescribing Information for XTANDI](#).



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