

PATIENT INFORMATION

XTANDI® (ex TAN dee)
(enzalutamide)
capsules

XTANDI® (ex TAN dee)
(enzalutamide)
tablets

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.

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

Before taking XTANDI, 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 history of heart disease.
- have high blood pressure.
- 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 of XTANDI.
 - 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.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. XTANDI may affect the way other medicines work, and other medicines may affect how XTANDI works.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed XTANDI.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist when you get a new medicine.

How should I take XTANDI?

- Take XTANDI exactly as your healthcare provider tells you.
- Take your prescribed dose of XTANDI 1 time a day, at the same time each day.
- Your healthcare provider may change your dose if needed.
- Do not change or stop taking your prescribed dose of XTANDI without talking with your healthcare provider first.
- XTANDI can be taken with or without food.
- Swallow each XTANDI capsule or tablet 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 healthcare provider may change your treatment to a smaller tablet size or stop your treatment with XTANDI if you have swallowing problems with capsules or tablets.
- If you are receiving gonadotropin-releasing hormone (GnRH) therapy, you should continue with this treatment during your treatment with XTANDI unless you have had a 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 healthcare provider 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. 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 loss of consciousness or 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 healthcare provider 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 healthcare provider 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 healthcare provider will monitor you for signs and symptoms of heart problems during your treatment with XTANDI. Call your healthcare provider or go to the nearest 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 (fainting) or seizures. Your healthcare provider 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. See “How should I take XTANDI?”

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

The most common side effects of XTANDI include:

- muscle and joint pain
- feeling more tired than usual
- hot flashes
- constipation
- decreased appetite
- diarrhea
- high blood pressure
- bleeding problems
- falls
- bone fractures
- headache

XTANDI 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.

These are not all of the possible side effects of XTANDI. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store XTANDI?

- XTANDI capsules and tablets come in a child-resistant bottle.
- Store XTANDI capsules and tablets between 68°F to 77°F (20°C to 25°C).
- Keep XTANDI capsules and tablets dry and in a tightly closed container.

Keep XTANDI and all medicines out of the reach of children.

General information about the safe and effective use of XTANDI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use XTANDI for a condition for which it was not prescribed. Do not give XTANDI to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about XTANDI that is written for health professionals.

What are the ingredients in XTANDI?

XTANDI capsules

Active ingredient: enzalutamide

Inactive ingredients: caprylocaproyl polyoxylglycerides, butylated hydroxyanisole, butylated hydroxytoluene, gelatin, sorbitol sorbitan solution, glycerin, purified water, titanium dioxide, black iron oxide.

XTANDI tablets

Active ingredient: enzalutamide

Inactive ingredients: hypromellose acetate succinate, microcrystalline cellulose, colloidal silicon dioxide, croscarmellose sodium, and magnesium stearate.

The tablet film-coat contains hypromellose, talc, polyethylene glycol, titanium dioxide, and ferric oxide.

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For more information go to www.Xtandi.com or call 1-800-727-7003.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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