



Starting treatment with XTANDI

XTANDI (enzalutamide) capsules is a prescription medicine used to treat men with castration-resistant prostate cancer (prostate cancer that is resistant to medical or surgical treatments that lower testosterone) that has spread to other parts of the body and who have received treatment with docetaxel.

As you start XTANDI (ex TAN dee), it is important to learn what you can expect with treatment. Talking with your doctor and nurse, and reading this leaflet are a great way to start. Remember to take your XTANDI capsules as prescribed, and continue to talk with your doctor or nurse about any questions or concerns.

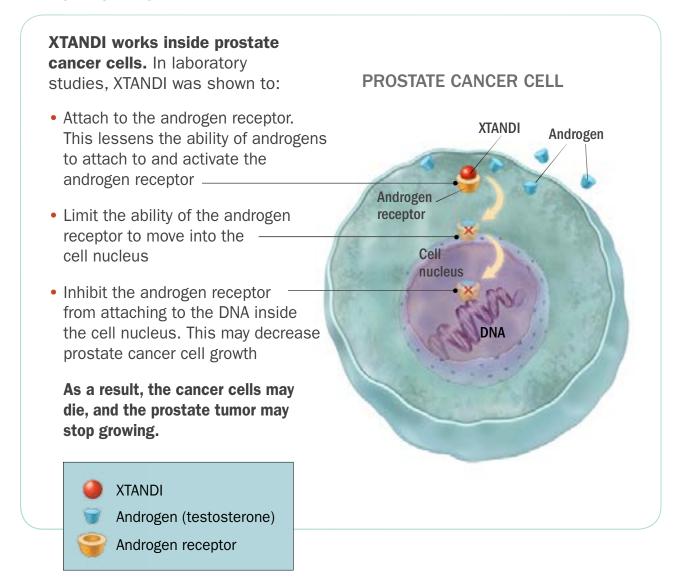


Continuing to fight my prostate cancer with **XTANDI** capsules. Continuing to do what matters to me.

XTANDI may cause side effects, including seizure. Please see the Full Prescribing Information on <u>AboutXtandi.com</u> for complete safety information on XTANDI.

How XTANDI works

XTANDI is in a class of medicines called *androgen receptor inhibitors*. Androgens, such as testosterone, are male hormones. To understand how XTANDI works, it's important to know that androgens play a role in prostate cancer cell growth. Androgens attach to and activate androgen receptors, which may result in the cancer cells dividing and growing.



Select Safety Information

Tell your healthcare provider about all medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. XTANDI can interact with many other medicines.

Please see the Full Prescribing Information on <u>AboutXtandi.com</u> for complete safety information on XTANDI (enzalutamide) capsules.

For more information, tips, and resources to help you stay on track and manage side effects, please visit AboutXtandi.com.



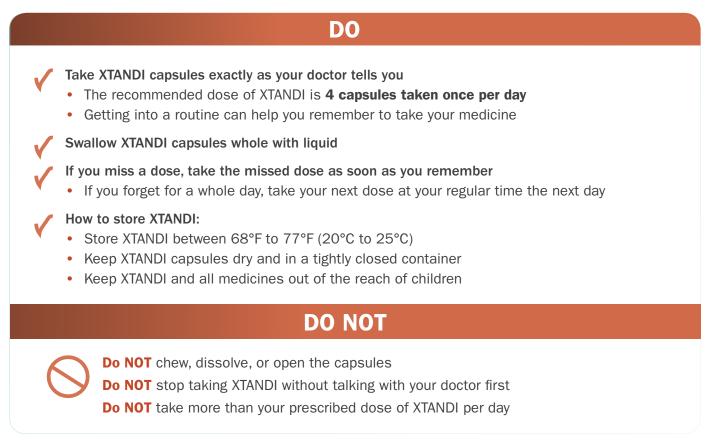
How to take **XTANDI**

It is important to take XTANDI exactly as your doctor tells you. **The recommended dose is 4 capsules taken with water once a day.** Swallow capsules whole. Do not stop taking XTANDI without talking with your doctor first.

XTANDI can be taken with or without food. Always talk with your doctor if you have any questions or concerns about your treatment with XTANDI. The recommended dose is



Important points to remember



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Possible side effects with XTANDI

XTANDI may cause side effects. Be sure to always talk with your doctor or nurse about any side effects you may be concerned about.

Possible serious side effect

XTANDI may cause serious side effects, including seizure. Some people have had seizures during treatment with XTANDI (7 of 800 patients in a clinical trial). 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.

The most common side effects of XTANDI:

The most common side effects of XTANDI and how often they occurred are listed below.

Side effects that happened in a clinical study of XTANDI	Percentage of men taking XTANDI who had these side effects (of 800 patients)	Percentage of men taking placebo* who had these side effects (of 399 patients)
Weakness or fatigue	50.6%	44.4%
Back pain	26.4%	24.3%
Diarrhea	21.8%	17.5%
Pain in your joints	20.5%	17.3%
Hot flashes	20.3%	10.3%
Swelling in your hands, arms, legs, or feet	15.4%	13.3%
Muscle or bone pain	15.0%	11.5%
Headache	12.1%	5.5%
Cold like symptoms	10.9%	6.5%
Muscle weakness	9.8%	6.8%
Dizziness	9.5%	7.5%
Trouble falling or staying asleep	8.8%	6.0%
Trouble breathing	8.5%	4.8%
Back pain with nerve problems in the lower body, including leg numbness or weakness	7.4%	4.5%
Pink or red urine	6.9%	4.5%
Sensation of tingling, burning, pricking, or numbness of skin	6.6%	4.5%
Anxiety	6.5%	4.0%
High blood pressure	6.4%	2.8%

Tell your doctor if you have any falls or problems thinking clearly. Tell your doctor if you have any side effect that bothers you or that does not go away.

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

You are encouraged to report negative side effects of prescription drugs to the FDA.Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

*Placebo is a capsule with no active medicine.

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Take an active role in your care

Your cancer care involves a team of people. As part of that team, YOU are in charge of taking your medicine every day. To get the most out of your treatment, you need to take XTANDI capsules exactly as your healthcare team tells you.

The following tips may also help you stay on track with XTANDI:



Keep your medicine in a pillbox.



Make reminders to take your medicine the same time each day.



Use a calendar or tracker.

Getting XTANDI

Your doctor is your main source of information about treatment with XTANDI. Your doctor, nurse, or other clinical office staff may have your XTANDI prescription filled at a specialty pharmacy (not at a local retail pharmacy) or at your doctor's in-office pharmacy. If you are having problems finding out what your insurance covers or paying for your medicine, first talk with your doctor or nurse. You or your doctor's office can also contact XTANDI Access Services at 1-855-898-2634.

XTANDI Access Services[™] may find ways to help you pay for XTANDI^{*}:

- If you do not have insurance
- If your insurance does not cover XTANDI
- If you cannot afford your monthly costs for XTANDI

XTANDI Access Services can help you find out what you will be expected to pay and what your insurance may cover. This includes coverage with Medicare, Medicaid, private insurance, and TRICARE. You can also get help finding the right specialty pharmacy to fill your XTANDI prescription.

For more information about XTANDI Access Services, call 1-855-8XTANDI (1-855-898-2634) (9 AM to 8 PM eastern time, Monday through Friday) or visit XtandiAccessServices.com.

*Eligibility rules apply. Void where prohibited by law.

XTANDI Access Services[™] is a component of Astellas Access Services[™].

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Important Safety Information

Who should not take XTANDI?

XTANDI is not for use in women. Do not take XTANDI if you are pregnant or may become pregnant. XTANDI may harm your unborn baby. It is not known if XTANDI is safe and effective in children.

Before you take XTANDI, tell your healthcare provider if you:

- Have a history of seizures, brain injury, stroke, brain tumors.
- Have any other medical conditions.
- Have a partner who is pregnant or plans to become pregnant. Men who are sexually active with a pregnant woman
 must use a condom during and for 3 months after treatment with XTANDI. If their sexual partner may become
 pregnant, a condom and another form of birth control must be used during and for 3 months after treatment.
 Talk with your healthcare provider if you have questions about birth control. See "Who should not take XTANDI?"
- Take any other medicines, including prescription and non-prescription medicines, vitamins, and herbal supplements. XTANDI can interact with many other medicines. You should not start or stop any medicine before you talk with the healthcare provider that prescribed XTANDI.

How should I take XTANDI?

- Take XTANDI capsules exactly as your healthcare provider tells you.
- Take your prescribed dose of XTANDI one time a day.
- Your healthcare provider may change your dose if needed.
- Do not stop taking your prescribed dose of XTANDI without talking with your healthcare provider first.
- XTANDI capsules can be taken with or without food.
- Swallow XTANDI capsules whole. Do not chew, dissolve, or open the capsules.
- 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.
- If you take too much XTANDI, call your healthcare provider or go to the nearest emergency room right away.

What are the possible side effects of XTANDI?

XTANDI may cause serious side effects including:

• Seizure. Some people have had seizures during treatment with XTANDI (7 of 800 in a clinical trial). 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.

The most common side effects of XTANDI include weakness or feeling more tired than usual, back pain, diarrhea, pain in your joints, hot flashes, swelling in your hands, arms, legs or feet, muscle or bone pain, headache, cold like symptoms, muscle weakness, dizziness, trouble falling or staying asleep (insomnia), trouble breathing (pneumonia), back pain with nerve problems in the lower body, including leg numbness or weakness, pink or red urine (hematuria), sensation of tingling, burning, pricking, or numbness of skin (paresthesia), anxiety, and high blood pressure (hypertension).

Tell your healthcare provider if you have any falls or problems thinking clearly. 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 XTANDI. For more information, ask your healthcare provider or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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