




Getting Started on XTANDI

Who is XTANDI for? XTANDI is a prescription medicine used to treat men with prostate cancer that no longer responds to a medical or surgical treatment that lowers testosterone and that has spread to other parts of the body. (This is a type of advanced prostate cancer.)

Select Safety Information

Who should not take XTANDI? XTANDI is not for use in women. Women should not take XTANDI if they are pregnant or may become pregnant. XTANDI can harm an unborn baby. It is not known if XTANDI is safe and effective in children.

Please see Important Safety Information for XTANDI on pages 25–29 and accompanying Full Prescribing Information in the back pocket.

 **Xtandi.**
(enzalutamide)
40 mg capsules

ABOUT XTANDI



XTANDI is FDA-approved to treat men with a type of advanced prostate cancer that no longer responds to a medical or surgical treatment that lowers testosterone and that has spread to other parts of the body.



XTANDI was researched in one study to find out if it may help men live longer and/or slow cancer progression. Learn about these results on page 8.



XTANDI was researched in an additional study against another common treatment for advanced prostate cancer. Learn about these results on page 9.



XTANDI may cause side effects—learn more on page 10. Talk with your healthcare team about any side effect that bothers you, or you may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



Steroids, for example oral prednisone, can be taken but are not required with XTANDI. Talk with your urologist or oncologist if you have questions about steroids.



Answers to your XTANDI questions are just a phone call away.
Call 1-855-8XTANDI (1-855-898-2634) anytime.

Understanding advanced prostate cancer and XTANDI

When prostate cancer first develops, it is only found in the prostate. But sometimes even with treatment to control the cancer, it can get worse or advance.

XTANDI is FDA-approved to treat a type of advanced prostate cancer that:

- No longer responds to a medical or surgical treatment that lowers testosterone, and
- Has spread, or metastasized, beyond the prostate to other areas of the body



“ I reached a point where I needed to do something else. That’s when my doctor and I started talking about XTANDI. ”

—David, treated with XTANDI

Go to XTANDI.com/videos to hear David’s XTANDI story.

Important safety information to tell your doctor before starting XTANDI

Before you take XTANDI, tell your doctor if you have a history of seizures, brain injury, stroke, or brain tumors; have any other medical conditions; or have a pregnant partner or a partner who may become pregnant. Tell your doctor if you take any other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. You should not start or stop any medicine before you talk with your doctor.

ONCE-DAILY
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ABOUT XTANDI

How XTANDI is thought to work within prostate cancer cells

XTANDI is what is called an androgen receptor inhibitor. Androgens are a group of hormones that includes testosterone. Androgen receptor inhibitors interfere with the connection between androgens and androgen receptors. This can help slow cancer cell growth.

Imagine the inside of a prostate cancer cell as a puzzle:

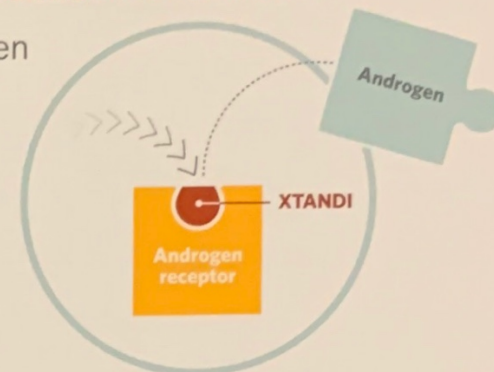
Prostate cancer cell

When the androgen connects with the androgen receptor, it may cause the tumor cells to grow.



XTANDI in a prostate cancer cell

Decreasing how often the androgen can connect with the androgen receptor may reduce tumor growth.



This is how XTANDI was shown to work in laboratory studies.

As a result, the cancer cells may die and the prostate tumor may stop growing.

Select Safety Information

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. Your healthcare provider will stop XTANDI if you have a seizure during treatment. If you take XTANDI you may be at risk of developing a condition involving the brain called Posterior Reversible Encephalopathy Syndrome (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. Your healthcare provider will stop XTANDI if you develop PRES.

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HOW XTANDI MAY HELP

XTANDI fights advanced prostate cancer

A study of 1,717 men with advanced prostate cancer compared men taking XTANDI with men not taking XTANDI. These men had not received treatment with chemotherapy and had prostate cancer that had spread to other parts of the body. Men also received hormone therapy injections during the course of this study.

During this study, XTANDI:



Slowed the progression of advanced prostate cancer

Men taking XTANDI had an 83% lower chance of their cancer progressing compared with men not taking XTANDI.*



Helped men live longer

Men taking XTANDI lived longer than men not taking XTANDI. The median overall survival was 35 months for men taking XTANDI vs 31 months for men not taking XTANDI.

During the study, XTANDI also delayed the time to start chemotherapy

XTANDI delayed the time before patients began chemotherapy by a median of 28 months vs 11 months for men not taking XTANDI. The median is the middle number of a group of numbers.

*In this study, 86% of patients taking XTANDI did not see their cancer get worse vs 60% of patients not taking XTANDI. In the study, progression was defined as the cancer getting worse, as measured by scans, or if the patient died for any reason.

XTANDI may cause serious side effects. Please see Important Safety Information for XTANDI on pages 25–29 and accompanying Full Prescribing Information in the back pocket.

XTANDI was also studied to understand how well it slows progression when compared against bicalutamide

A study of 375 men with advanced prostate cancer compared 184 men who were taking XTANDI with 191 men who were taking bicalutamide. These men had not received treatment with chemotherapy and had prostate cancer that had spread to other parts of the body. Men also received hormone therapy injections during the course of this study.

During this study, XTANDI slowed the progression of advanced prostate cancer compared with bicalutamide

Men taking XTANDI had a 40% lower chance of their cancer progressing than men taking bicalutamide.*

Select Safety Information

In this study, the most common side effects patients taking XTANDI experienced more than patients taking bicalutamide were fatigue, hot flashes, high blood pressure, diarrhea, weight loss, and pain in the extremities.

**Questions about
XTANDI?**

**Talk with your doctor or call XTANDI Support Solutions at
1-855-8XTANDI (1-855-898-2634) to learn more.**

*In the study, progression was defined as the cancer getting worse, as measured by scans, or if the patient died for any reason.

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SIDE EFFECTS

XTANDI may cause serious side effects

If you take XTANDI, you may be at risk of having a seizure.

- In studies comparing XTANDI with placebo, 8 out of 1,671 patients taking XTANDI had a seizure and 1 out of 1,243 patients taking placebo had a seizure
- In a separate study comparing XTANDI with bicalutamide, 3 out of 380 patients taking XTANDI had a seizure and 1 out of 387 patients taking bicalutamide had a seizure

Avoid activities where losing consciousness could seriously harm you or someone else. Tell your doctor right away if you lose consciousness or have a seizure. Your doctor will stop XTANDI if you have a seizure during treatment.

Since XTANDI was FDA-approved in 2012, there have been reports of XTANDI patients developing a condition involving the brain called Posterior Reversible Encephalopathy Syndrome (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. Your healthcare provider will stop XTANDI if you develop PRES.

Looking for help?

Tips for managing weakness or feeling tired are on page 22.

The most common side effects of XTANDI

- Weakness or feeling more tired than usual
- Back pain
- Decreased appetite
- Constipation
- Joint pain
- Diarrhea
- Hot flashes
- Upper respiratory tract infection
- Swelling in your hands, arms, legs, or feet
- Shortness of breath
- Muscle and bone pain
- Weight loss
- Headache
- High blood pressure
- Dizziness
- A feeling that you or things around you are moving or spinning (vertigo)

XTANDI may cause infections, falls, and injuries from falls. Tell your doctor if you have signs or symptoms of an infection or if you fall.

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.

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.

What to tell your doctor before starting XTANDI

Tell your doctor if you:

Have a history of seizures, brain injury, stroke, or brain tumors

Have any other medical conditions

Have a partner who is pregnant or may become pregnant

- If you are sexually active with a pregnant woman, you must use a condom during treatment with XTANDI and for 3 months after treatment
- If you have a partner who may become pregnant, use a condom and another form of birth control during treatment with XTANDI and for 3 months after treatment

Take other medicines

XTANDI may affect the way other medicines work, and other medicines may affect the way XTANDI works. That's why it's important to tell your doctor about all the medicines you take. This includes prescription and over-the-counter medicines, including vitamins and herbal supplements. Keep a list of all your medications, and inform your doctor before making any changes to your treatment routine.

How to take XTANDI

XTANDI is taken once a day, at the same time each day. It's important to take XTANDI exactly as prescribed by your doctor.



The recommended dose of XTANDI is four 40-mg capsules, for a total dose of 160 mg. Your doctor will change your dose if needed. Do not change or stop taking your prescribed dose of XTANDI without talking with your doctor first.



XTANDI must be swallowed whole with fluids, like water or juice. Do not chew, dissolve, or open the capsules.



XTANDI can be taken with or without food. This gives you the flexibility to plan your daily dose around your own schedule. Just remember to take XTANDI at the same time each day.

Try the tips below to help you take your medicine as directed by your doctor:



Take XTANDI when you do another daily activity, such as after brushing your teeth.



Download the XTANDI treatment tracking calendar on XTANDI.com/calendar.



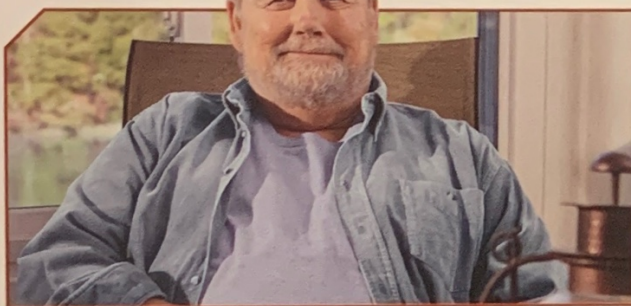
Set an alarm to help you remember to take XTANDI at the same time each day.

TAKING XTANDI

What to do if you miss a dose

Missed your regular treatment time	Take XTANDI as soon as you remember that same day.
Missed by 1 day	Take your normal dose of XTANDI at your regular time the next day.

Remember, you should only take your prescribed dose of XTANDI once per day. **If you take too much XTANDI in 1 day, contact a member of your healthcare team or go to the nearest emergency room right away. You may have an increased risk of seizure if you take too much XTANDI.**



“ My doctor told me that as long I take XTANDI daily, I can take it before a meal or after a meal. ”

—David, treated with XTANDI

Go to [XTANDI.com/videos](https://www.xtandi.com/videos) to hear David's XTANDI story.

Assessing your prostate cancer while taking XTANDI

A PSA (prostate-specific antigen) test is often used to help diagnose prostate cancer, and it can also be used after diagnosis to help monitor your cancer response or progression. Although a PSA test can be helpful, it will not provide you and your doctor with a complete picture of your cancer. Aside from a PSA test, other tests—such as a computed tomography (CT) scan, magnetic resonance imaging (MRI) scan, or a bone scan—and physical exams can help your doctor assess your cancer.

Did you know?

Because a single PSA test will not give you a complete picture of your cancer, it's important to talk with your doctor about other tests that can be used to monitor your prostate cancer.

How to store XTANDI

Store XTANDI in a dry place that stays between 68°F and 77°F (20°C and 25°C). Always keep XTANDI dry and in a tightly closed container, and out of the reach of children.

HOW TO GET XTANDI

There are 2 ways to get XTANDI:

It's important to know that XTANDI is not available at your local drugstore.

1 Specialty pharmacy

In most cases, your doctor will send your XTANDI prescription to a specialty pharmacy. A specialty pharmacy fills prescriptions for certain medicines that are not available at regular drugstores. One benefit of getting XTANDI from a specialty pharmacy is that your medicine will be mailed right to your home. The specialty pharmacy will call you to arrange the delivery of your medicine.

Specialty pharmacies may also offer other services to assist you. These include helping you understand your insurance coverage and finding programs that may offer financial assistance if you can't afford your co-pay or medicine.* They can also provide you with helpful information about XTANDI.

2 Pharmacy in your doctor's office

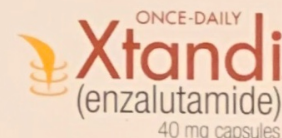
In some cases, your doctor's office may have its own pharmacy that can fill your XTANDI prescription.

*Subject to eligibility. Restrictions may apply.



Our dedicated access specialists at XTANDI Support Solutions can help you get XTANDI.

Go to page 20 or call 1-855-8XTANDI (1-855-898-2634) to learn more.



HOW TO GET XTANDI

Getting XTANDI from a specialty pharmacy

Here's how the process typically works, and a few tips to help ensure it goes as smoothly as possible.



At your doctor's office: A member of your healthcare team will fill out the required insurance paperwork with you and then send your prescription for XTANDI to a specialty pharmacy or XTANDI Support Solutions to help with the process.

Tip At your appointment, confirm that your insurance paperwork is complete.



A few days after your appointment: The specialty pharmacy will call you about your out-of-pocket costs and arrange the delivery of your medicine. You may also receive a call from XTANDI Support Solutions if there are any questions with the insurance paperwork.

Tip Reach out to your doctor if you haven't heard from your specialty pharmacy within a few days.



When it's time for delivery: XTANDI may be delivered right to your home or office.



When it's time for a refill: Your specialty pharmacy will call you to arrange a refill.

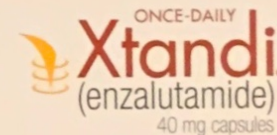
Tip If you haven't received your medicine, call your healthcare provider or specialty pharmacy.

Tip Contact your specialty pharmacy 2 weeks before your medicine is going to run out if you have not heard from them.



XTANDI Support Solutions can help you get XTANDI.

All you have to do is call 1-855-8XTANDI (1-855-898-2634).
Our dedicated access specialists are here to help.



XTANDI SUPPORT SOLUTIONS



One phone number, lots of answers—call 1-855-8XTANDI (1-855-898-2634)

XTANDI Support Solutions is dedicated to helping you get the support you need. With us, you'll have 24/7 access to resources to help you get started on XTANDI and stay on track. Whether you need help finding financial assistance or have questions about XTANDI, call **1-855-8XTANDI (1-855-898-2634)** to get in touch with a dedicated access specialist or nurse.

Help getting and paying for XTANDI

Our dedicated access specialists can help you navigate the process of getting started on XTANDI, from arranging the delivery of your medicine to helping you find ways to pay for it.* They are available Monday through Friday from 8 AM to 8 PM ET.

Our dedicated access specialists also can assist in finding you financial support based on your unique situation:

- If you are a new patient or your insurance changes
- If you have insurance from your employer or you are self-insured
- If you don't have insurance or XTANDI is not covered
- If you have Medicare, Medicaid, or TriCare®

Pay no more than

\$20 per month

for your XTANDI
prescription*

You may be eligible to pay no more than \$20 per month for your XTANDI prescription.* Call XTANDI Support Solutions at **1-855-8XTANDI (1-855-898-2634)** to find out if you qualify.

*Subject to eligibility. Restrictions may apply.

24/7 phone support from our team of nurses



Call anytime to speak with a nurse who is working on behalf of Astellas and Medivation. **Talking to our nurses should not replace the advice of your healthcare team.** Our nurses are available day and night to help answer your questions about:

- How XTANDI works
- Taking XTANDI
- Adding XTANDI to your daily routine
- How XTANDI may help
- Possible side effects of XTANDI*

***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.**



“ It’s great to know someone is there who can help answer your questions about XTANDI 24/7. ”

—Theresa, caring for her husband Dennis

Go to XTANDI.com/videos to hear Theresa’s story.

HELP WITH MANAGING WEAKNESS OR FEELING TIRED

Tips to discuss with your doctor

These tips come from organizations that focus on supporting people with cancer. These tips have not been studied with XTANDI, but they may be able to help you manage weakness or feeling tired. **You should always talk with your healthcare team before deciding if any of these tips are right for you.**

Weakness



Drink plenty of fluids, especially water.

Your body needs water to do its work. Talk to your healthcare team about how much water to drink each day.



Stay active.

Try going for short walks or doing light stretching exercises. Talk with your healthcare team about other types of exercise that may help you feel better.



Get a good night's sleep.

If you feel tired during the day, it's okay to rest and take a nap. Try to keep your naps short and early in the day so they don't interfere with nighttime sleep.

Feeling tired



Try to exercise.

Exercise can help you feel better both physically and mentally. If you decide to exercise, make sure to check with your doctor about healthy ways to add it to your routine.



Focus on relaxing.

If you're feeling stressed, it might help if you talk to other men living with advanced prostate cancer. Support groups can be a great place to start. You can also try doing things that can help you relax but that require little energy, like reading, listening to music, or meditating.



Stick with a consistent sleep schedule.

Try to sleep 7 to 8 hours each night. Also, try to limit your naps to under 30 minutes. If you can, avoid foods and drinks that are high in caffeine at night.



Talk with your healthcare team or dietician about managing your diet.

Work with them to create an eating plan that includes the right amount of nutrients and fluids your body needs.

IMPORTANT SAFETY INFORMATION

WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING XTANDI?

Tell your doctor if you:



Have a history of seizures, brain injury, stroke, or brain tumors



Have any other medical conditions



Have a partner who is pregnant or may become pregnant

If you have a pregnant partner, it's important to know that XTANDI can harm a baby in the womb. If you are sexually active with a pregnant woman, you must use a condom during treatment. Also use a condom for 3 months after treatment with XTANDI.

If you have a partner who may become pregnant, use a condom and another form of birth control while taking XTANDI. If you stop taking XTANDI, you should keep using 2 forms of birth control for at least 3 months before planning a pregnancy. Talk with your doctor if you have questions about birth control.



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 every day exactly as your doctor tells you

Take all your prescribed dose once a day, at the same time each day. Swallow XTANDI capsules whole. Do not chew, dissolve, or open the XTANDI capsules. XTANDI can be taken with or without food. Your doctor may change your dose if needed.



If you miss a dose of XTANDI:

Take your prescribed dose as soon as you remember that day. If you miss a daily dose, just take XTANDI at your regular time the next day. Do not take more than your prescribed dose in one day. If you take too much XTANDI, call your doctor or go to the nearest emergency room right away. Taking too much XTANDI may increase your risk of having a seizure.



Do not change or stop taking your prescribed dose of XTANDI without talking with your doctor first

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 losing consciousness could seriously harm you or someone else. Tell your doctor right away if you lose consciousness or have a seizure. Your doctor will stop XTANDI if you have a seizure during treatment.

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. Your healthcare provider will stop XTANDI if you develop PRES.



The most common side effects of XTANDI include:

- weakness or feeling more tired than usual
- back pain
- decreased appetite
- constipation
- joint pain
- diarrhea
- hot flashes
- upper respiratory tract infection
- swelling in your hands, arms, legs, or feet
- shortness of breath
- muscle and bone pain
- weight loss
- headache
- high blood pressure
- dizziness
- vertigo (a feeling that you or things around you are moving or spinning)

XTANDI may cause infections, falls and injuries from falls. Tell your doctor if you have signs or symptoms of an infection or if you fall.

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.

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.