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How XTANDI May Help



The effectiveness of XTANDI was proven in 2 global clinical studies



PREVAIL



AFFIRM

The PREVAIL study included 1,717 patients who:

- Had prostate cancer that had spread to other parts of the body
- Were no longer responding to a medical or surgical treatment to lower their testosterone
- Had not received chemotherapy

The AFFIRM study included 1,199 patients who:

- Had prostate cancer that had spread to other parts of the body
- Were no longer responding to a medical or surgical treatment to lower their testosterone
- Had previously received treatment with docetaxel, a type of chemotherapy

Patients taking XTANDI who were already receiving hormone therapy injections continued to do so during these studies. Patients not taking XTANDI also received hormone therapy injections.

Clinical study results

XTANDI significantly slowed the progression of advanced prostate cancer

During the PREVAIL study,

Patients taking XTANDI had an 83% lower chance* of their cancer getting worse[†] or of dying, compared with patients not taking XTANDI.

XTANDI was shown to improve overall survival in many patients

During the PREVAIL study,

Patients taking XTANDI had a 23% lower chance[‡] of dying than patients not taking XTANDI.

During the AFFIRM study,

Patients taking XTANDI had a 37% lower chance[§] of dying than patients not taking XTANDI.

*14% of patients taking XTANDI saw their cancer progress or died during the study vs 40% of patients not taking XTANDI.

[†]Based on scans.

[‡]58% of patients taking XTANDI remained alive during the study (or were not available for follow-up) vs 51% of patients not taking XTANDI.

[§]62% of patients taking XTANDI remained alive during the study (or were not available for follow-up) vs 47% of patients not taking XTANDI.

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.

XTANDI significantly delayed the median time before patients began chemotherapy

Not taking XTANDI

11 MONTHS



28 MONTHS

During the PREVAIL study, the median time until the start of chemotherapy was 28 months for patients taking XTANDI vs 11 months for patients not taking XTANDI.

Select Safety Information

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.



Questions about paying for XTANDI?



Learn how to take XTANDI

Next: Side Effects

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.)

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 can 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 or brain tumors.

Have any other medical conditions.

Have a partner who is pregnant or may 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 your 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 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.

How should I take XTANDI?

Take XTANDI exactly as your healthcare provider tells you.

Take your prescribed dose of XTANDI one 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 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 in one 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. Your healthcare provider 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, loss of taste, loss of appetite, and loss of energy. Tell your healthcare provider if you experience any of these side effects.



XTANDI may cause infections, falls and injuries from falls. Tell your healthcare provider 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.

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.

Please see the [Full Prescribing Information](#) for complete prescribing information.

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