

16 HOW SUPPLIED/STORAGE AND HANDLING

XTANDI (enzalutamide) 40 mg capsules are supplied as white to off-white oblong soft gelatin capsules imprinted in black ink with ENZ. XTANDI capsules are available in the following package sizes:

- Bottles of 120 capsules (NDC 0469-0125-99)

Recommended storage: Store XTANDI capsules at 20°C to 25°C (68°F to 77°F) in a dry place and keep the container tightly closed. Excursions permitted from 15°C to 30°C (59°F to 86°F).

Do not chew, dissolve or open the capsules.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the [FDA-approved patient labeling \(Patient Information\)](#).

Seizure

- Inform patients that XTANDI has been associated with an increased risk of seizure. Discuss conditions that may predispose to seizures and medications that may lower the seizure threshold. Advise patients of the risk of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others. Inform patients to contact their healthcare provider right away if they have loss of consciousness or seizure [*see Warnings and Precautions (5.1)*].

Posterior Reversible Encephalopathy Syndrome (PRES)

- Inform patients to contact their healthcare provider right away if they experience rapidly worsening symptoms possibly indicative of PRES such as seizure, headache, decreased alertness, confusion, reduced eyesight, or blurred vision [*see Warnings and Precautions (5.2)*].

Hypersensitivity

- Inform patients that XTANDI may be associated with hypersensitivity reactions that include swelling of the face, lip, tongue, or throat [*see Warnings and Precautions (5.3)*]. Advise patients who experience these types of symptoms of hypersensitivity to discontinue XTANDI and promptly contact their healthcare provider.

Ischemic Heart Disease

- Inform patients that XTANDI has been associated with an increased risk of ischemic heart disease. Advise patients to seek immediate medical attention if any symptoms suggestive of a cardiovascular event occur [*see Warnings and Precautions (5.4)*].

Falls and Fractures

- Inform patients that XTANDI is associated with an increased incidence of dizziness/vertigo, falls, and fractures. Advise patients to report these adverse reactions to their healthcare provider [*see Warnings and Precautions (5.5)*].

Hypertension

- Inform patients that XTANDI is associated with an increased incidence of hypertension [*see Adverse Reactions (6.1)*].

Dosing and Administration

- Inform patients who have not undergone bilateral orchiectomy and are receiving GnRH therapy that they need to maintain this treatment during the course of treatment with XTANDI.
- Instruct patients to take their dose at the same time each day (once daily). XTANDI can be taken with or without food. Each capsule should be swallowed whole. Do not chew, dissolve, or open the capsules.
- Inform patients that they should not interrupt, modify the dose, or stop XTANDI without first consulting their healthcare provider.
- Inform patients that if they miss a dose, then they should take it as soon as they remember. If they forget to take the dose for the whole day, then they should take their normal dose the next day. They should not take more than their prescribed dose per day [*see Dosage and Administration (2.1)*].

Embryo-Fetal Toxicity

- Inform patients that XTANDI can be harmful to a developing fetus and can cause loss of pregnancy.
- Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of XTANDI. Advise male patients to use a condom if having sex with a pregnant woman [*see Warnings and Precautions (5.6)*].

Infertility

- Inform male patients that XTANDI may impair fertility [*see Use in Specific Populations (8.3)*].

Manufactured for and Distributed by: Astellas Pharma US, Inc., Northbrook, IL 60062

Marketed by:

Astellas Pharma US, Inc., Northbrook, IL 60062 Pfizer Inc., New York, NY 10017
249693-XTA

Rx Only

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PATIENT INFORMATION

XTANDI® (ex TAN dee) (enzalutamide) capsules

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.

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 XTANDI capsules whole. Do not chew, dissolve, or open the capsules.
- 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 fractures.** XTANDI treatment may increase your risk for falls and fractures. Falls were not caused by loss of consciousness (fainting) or seizures. Your healthcare provider will monitor your risks for falls and fractures during treatment with XTANDI.

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

The most common side effects of XTANDI include:

- weakness or feeling more tired than usual
- back pain
- hot flashes
- constipation
- joint pain
- decreased appetite
- diarrhea
- high blood pressure

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 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?

- Store XTANDI between 68°F to 77°F (20°C to 25°C).
- Keep XTANDI capsules 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?

Active ingredient: enzalutamide

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

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

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