

Enzalutamide (Xtandi)

About This Medicine

ENZALUTAMIDE (EN za LOO ta mide) treats prostate cancer. It works by blocking the effect of testosterone and other hormones in your body, which may slow or stop cancer cells from spreading or growing. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Diarrhea (loose bowel movements)
- Constipation (unable to move bowels)
- Tiredness
- Decreased appetite (decreased hunger)
- Abnormal bleeding – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding.
- Bone and muscle pain
- Risk of falls and/or fractures
- Headache
- High blood pressure
- Hot flashes or sudden skin flushing may happen. You may also feel warm or red.

Note: Each of the side effects above was reported in 10% or greater of people treated with enzalutamide. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Seizure. Common symptoms of a seizure can include confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. There are other less common symptoms of seizures. **If you or your family member suspects you are having a seizure, call 911 right away.**

- Swelling in the brain that is usually reversible. Symptoms can be sudden (acute) and may include a headache, confusion, changes in eyesight, extreme tiredness/coma, and/or seizures. **If you start to have any of these symptoms let your care team know right away.**
- Risk of heart attack
- Increased risk of falls and fractures
- Allergic reactions are rare but may happen in some patients. Signs of allergic reaction to this medicine may be swelling of the face, feeling like your lip/tongue or throat are swelling. **If this happens, do not take another dose of this medicine. You should get urgent medical treatment.**
- Swallowing problems and/or choking, which can be life-threatening, can happen due to the size of the capsules and/or tablets. Make sure you swallow this medicine with enough water and let your care team know if you have trouble swallowing it.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

Important Information

- Do not stop taking enzalutamide without first talking with your care team.
- If you are receiving gonadotropin-releasing hormone (GnRH) analog therapy, you should continue with this treatment during your treatment with enzalutamide. Talk to your care team about specific instructions.
- This medicine may impair your ability to drive or use machinery. Do not participate in activities where a sudden loss of consciousness could cause harm to you or others around you. Use caution and talk your care team about any precautions you may need to take.

How to Take Your Medicine

- Swallow the medicine whole with or without food. Take it with enough water to make sure you have swallowed the medicine successfully. Do not chew, open, or dissolve the capsules. Do not cut, crush, or chew the tablets.
- Take this medicine at the same time each day. If you are prescribed another medicine to take along with enzalutamide, take this medicine as prescribed by your care team.
- **Missed dose:** If you miss a dose, take it as soon as you think about it on the same day. If you forget to take your dose for the whole day, take your regular dose the next day at the regular time. Do not take more than one dose on the same day.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.



- **Storage:** Store this medicine in the original container at room temperature, in a dry place and keep the container tightly closed. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- Drink enough fluids to keep your urine pale yellow.
- If you have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicine that can lessen or stop your diarrhea and/or constipation.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your care team's approval, may increase your appetite.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

Food and Medicine Interactions

- There are no known interactions of enzalutamide with food.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with enzalutamide. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplement to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.
- There are known interactions of enzalutamide with blood thinning medicine such as warfarin. Ask your care team what precautions you should take.

When to Call Your Care Team



Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Confusion
- Extreme tiredness and/or coma
- Blurry vision or other changes in eyesight
- Headache that does not go away
- Feeling dizzy or lightheaded
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back or it can be constant. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Extreme weakness and tiredness that interferes with normal activities
- Pain that does not go away, or is not relieved by prescribed medicines
- Trouble swallowing
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Diarrhea 4 times in a day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Experience a fall
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Signs of allergic reaction: swelling of the face, feeling like your lip/tongue or throat are swelling. **If this happens, call 911 for emergency care.**

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can get your partner pregnant, use birth control while taking this medicine and for 3 months after the last dose. Tell your care team right away if you think your partner might be pregnant.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

Reviewed March 2026

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