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[Home](#) → [Drugs, Herbs and Supplements](#) → Enzalutamide

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## Enzalutamide

pronounced as (en" za loo' ta mide)

### Why is this medication prescribed?

Enzalutamide is used to treat prostate cancer that has spread to other parts of the body in men and who have been helped by certain medical and surgical treatments that decrease testosterone levels. It is also used to treat prostate cancer in men who have not been helped by certain medical and surgical treatments that decrease testosterone levels. Enzalutamide is in a class of medications called androgen receptor inhibitors. It works by blocking the effects of androgen (a male reproductive hormone) to stop the growth and spread of cancer cells.

### How should this medicine be used?

Enzalutamide comes as a tablet or a capsule to take by mouth. It is usually taken with or without food once a day. Take enzalutamide at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take enzalutamide exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the tablets or capsules whole; do not crush, chew, divide, dissolve, or open them.

Your doctor may tell you to stop taking enzalutamide for a short time or decrease your dose if you experience serious side effects during your treatment. Be sure to talk to your doctor about how you are feeling during your treatment with enzalutamide.

If your doctor has prescribed another medication such as degarelix (Firmagon), goserelin (Zoladex), histrelin (Supprelin LA, Vantas), leuprolide (Eligard, Lupron, in Lupaneta Pack), or triptorelin (Trelstar, Triptodur) to treat your prostate cancer, you will need to continue receiving this medication during your treatment with enzalutamide.

Continue to take enzalutamide even if you feel well. Do not stop taking enzalutamide without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

### Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking enzalutamide,

- tell your doctor and pharmacist if you are allergic to enzalutamide, any other medications, or any of the ingredients in enzalutamide tablets or capsules. Ask your pharmacist or check the manufacturer's information for the patient for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin, Jantoven), carbamazepine (Carbatrol, Equetro, Tegretol, others), clopidogrel (Plavix), cyclosporine (Gengraf, Neoral, Sandimmune), dihydroergotamine (D.H.E. 45, Migranal), ergotamine (in Migergot, in Cafergot), fentanyl (Actiq, Duragesic, Fentora, Subsys, others), gemfibrozil (Lopid), itraconazole (Onmel, Sporanox), omeprazole (Prilosec), midazolam, phenobarbital, phenytoin (Dilantin, Phenytek), pimozide (Orap), quinidine (in Nuedexta), rifabutin (Mycobutin, in Talicia), rifampin (Rimactane, in Rifamate, in Rifater), rifapentine (Priftin), sirolimus (Rapamune), and tacrolimus (Prograf). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with enzalutamide, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have or have ever had seizures, a brain injury, a brain tumor, a brain arteriovenous malformation (abnormal connection between arteries and veins in the brain that forms before birth and may cause bleeding in the brain), broken bones, osteoporosis (a condition in which the bones become thin and weak and break easily), diabetes, high cholesterol levels, high blood pressure, heart disease, or have had a stroke or ministroke.
- you should know that enzalutamide is *only* for use in men. Women should not take this medication, especially if they are or may become pregnant or are breast-feeding. Women, especially those who are or who may become pregnant should not touch enzalutamide capsules. If taken by pregnant women, enzalutamide may harm the fetus. If a pregnant woman takes enzalutamide, she should call her doctor immediately.
- you should know that this medication may decrease fertility in men. However, you should not assume that your female partner cannot become pregnant. If your partner is pregnant, you must use a condom whenever you have sex during your treatment with enzalutamide and for 3 months after your final dose. If your partner is not pregnant but could become pregnant, you must use effective birth control whenever you have sex during your treatment and for 3 months after your final dose.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking enzalutamide.
- you should know that enzalutamide may cause seizures. Do not drive a car or operate machinery until you know how this medication affects you.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if you do not remember until the next day, skip the missed dose and continue your regular dosing schedule. Do not take more than one dose in one day and do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Enzalutamide may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- weakness
- tiredness
- joint pain
- muscle weakness or stiffness
- weight loss
- loss of appetite
- headache
- dizziness
- burning, numbness, or tingling in the arms, hands, or feet
- decreased sense of touch or ability to feel sensation
- hot flashes
- difficulty falling asleep or staying asleep
- anxiety
- difficulty remembering, thinking, or paying attention
- diarrhea
- constipation
- itching
- dry skin
- nosebleeds
- frequent urination
- taste changes

**Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:**

- seizures
- headache; confusion; or vision changes
- swelling of the face, tongue, lips, throat, arms, legs, hands, or feet
- fever, cough, sore throat, or other signs of infection

- chest pain
- shortness of breath
- pain in the back, muscles, and/or legs
- numbness or tingling in the buttocks or legs
- difficulty controlling urination or bowel movements
- difficulty breathing
- falling
- broken bones or fractures
- hallucinating (seeing things or hearing voices that do not exist)
- breast enlargement in men
- pink or red urine

Enzalutamide may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## Symptoms of overdose may include the following:

- seizures

## What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Xtandi<sup>®</sup>

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