Enzalutamide (Xtandi®)

About This Drug

Enzalutamide is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Decrease in the number of white blood cells. This may raise your risk of infection.
- Diarrhea (loose bowel movements)
- Constipation (unable to move bowels)
- Tiredness and weakness
- Swelling in the legs, ankles and/or feet
- Upper respiratory infection
- Weight loss
- Electrolyte changes
- Decreased appetite (decreased hunger)
- Blood sugar levels may change. If you have diabetes, changes may need to be made to your diabetes medication.
- Back pain
- Joints, bone and muscle pain
- Feeling dizzy
- Headache
- Trouble breathing
- 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 patients treated with enzalutamide. Not all possible side effects are included above.

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.
• Changes in your central nervous system can happen. The central nervous system is made up of your brain and spinal cord. You could feel extreme tiredness, agitation, confusion, hallucinations (see or hear things that are not there), have trouble understanding or speaking, loss of control of your bowels or bladder, eyesight changes, numbness or lack of strength to your arms, legs, face, or body, seizures or coma. If you start to have any of these symptoms let your doctor know right away.

• Risk of heart attack

• Hypersensitivity reactions are rare but may happen in some patients. Signs of a hypersensitivity reaction to this drug 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 drug. You should get urgent medical treatment.

• Risk of falls and/or fractures

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

### Important Information

• This drug 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. This drug may also increase the risk of falling. Use caution and tell your nurse or doctor if you feel dizzy.

### How to Take Your Medication

• Swallow the medicine whole with or without food. Do not chew, open, or dissolve it.

• Take this medicine at the same time each day.

• **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 and contact your physician. Do not take 2 doses at the same time and do not double up on the next dose.

• If you vomit a dose, take your next dose at the regular time, and contact your physician.

• **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.

• Women whom are pregnant or may become pregnant should not handle your medicine because this drug can have harmful effects on the unborn baby, and/or can cause a loss of pregnancy.

• This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.

• **Storage:** Store this medicine in the original container at room temperature, in a dry place and keep the container tightly closed.

• **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 medication 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 nurse or your doctor how to dispose of unused medicine.

### Treating Side Effects

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• To decrease the risk of infection, wash your hands regularly.
• Avoid close contact with people who have a cold, the flu, or other infections.
• Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.
• Drink plenty of fluids (a minimum of eight glasses per day is recommended).
• If you throw up or have loose bowel movements, 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 get 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 nurse or doctor about medicine that can lessen or stop your diarrhea and/or constipation
• If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
• To help with decreased appetite, eat small, frequent meals.
• Eat high calorie food such as pudding, ice cream, yogurt and milkshakes.
• To help with weight loss, drink fluids that contribute calories (whole milk, juice, soft drinks, sweetened beverages, milkshakes, and nutritional supplements) instead of water.
• Include a source of protein at every meal and snack, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
• If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
• If you are dizzy, get up slowly after sitting or lying.
• Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
• Get regular exercise. If you feel too tired to exercise vigorously, try taking a short walk.

Food and Drug Interactions

• There are no known interactions of enzalutamide with food.
• Check with your doctor or pharmacist 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 drug interactions with enzalutamide. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplement to make sure that there are no interactions.
• The safety and use of dietary supplements and alternative diets are often not known. Using these might affect your cancer or interfere with your treatment. Do not use dietary supplements or alternative diets without your cancer doctor's help.
• Avoid the use of St. John’s Wort while taking enzalutamide as this may lower the levels of the drug in your body, which can make it less effective.
• There are known interactions of enzalutamide with blood thinning medicine such as warfarin. Ask your doctor what precautions you should take.

When to Call the Doctor
Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.5 F (38 C) or higher
- Chills
- Confusion and/or agitation
- Feeling dizzy or lightheaded
- Hallucinations
- Trouble understanding or speaking
- Blurry vision or changes in your eyesight
- Numbness or lack of strength to your arms, legs, face, or body
- Wheezing or trouble breathing
- 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.
- Coughing up yellow, green, or bloody mucus
- Extreme weakness that interferes with normal activities
- Pain that does not go away, or is not relieved by prescribed medicines
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Fatigue that interferes with your daily activities
- Diarrhea 4 times in a day or loose bowel movements with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Experience a fall
- Signs of a hypersensitivity reaction: swelling of the face, feeling like your lip/tongue or throat are swelling.
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- 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.
- If you think you may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning**: This drug can have harmful effects on the unborn baby. Enzalutamide is not indicated for use in women. Women who are or may become pregnant should not handle this drug. Men with female partners of childbearing potential should use effective contraception during your cancer treatment and for 3 months after your cancer treatment. Men should use a condom...
if having sex with a pregnant woman. Let your doctor know right away if you think you may have impregnated your partner.

- **Breastfeeding warning:** It is not known if this drug passes into breast milk. Enzalutamide is not indicated for use in women.

- **Fertility warning:** In men, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm banking.

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