

Darolutamide (Nubeqa)

About This Medicine

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

Possible Side Effects

- Decrease in the number of white blood cells, and red blood cells. This may raise your risk of infection and make you tired and weak.
- Constipation (not able to move bowels)
- Tiredness
- 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.
- Decreased appetite (decreased hunger)
- Weight gain
- Changes in your liver function
- Decreased level of calcium in your blood
- Blood sugar levels may change
- Pain in your leg, hand, arm and/or foot
- Rash
- High blood pressure

Note: Each of the side effects above was reported in 2% or greater of patients treated with darolutamide. 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 medical team.

Warnings and Precautions

- Risk of heart attacks
- 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.**

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

- If you are receiving gonadotropin-releasing hormone (GnRH) analog therapy, you should continue with this treatment during your treatment with darolutamide. Talk to your doctor and/or nurse about specific instructions.

How to Take Your Medicine

- Swallow this medicine whole with food.
- **Missed dose:** If you miss a dose, take it as soon as you remember before the next dose is due. Do not take 2 doses at the same time and do not double up on the next dose to make up for a missed dose.
- **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.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in 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 health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Keep the container tightly closed after opening.
- **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 nurse or your doctor 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.
- 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.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- Drink enough fluids to keep your urine pale yellow.
- Ask your doctor or nurse about medicines that are available to help stop or lessen constipation.



- 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 doctor's approval, may increase your appetite.
- 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.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.

Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- 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 medicine interactions with darolutamide. 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.
- 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.

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 100.4° F (38° C) or higher
- Chills
- A headache that does not go away
- Blurry vision or other changes in eyesight
- Tiredness that interferes with your daily activities
- 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.**
- No bowel movement in 3 days or when you feel uncomfortable



- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- 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
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Pain that does not go away, or is not relieved by prescribed medicines
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- If you think you may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on the unborn baby. Darolutamide is not indicated for use in women. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 1 week after stopping treatment. Let your doctor know right away if you think may have impregnated your partner.
- **Breastfeeding warning:** It is not known if this medicine passes into breast milk. Darolutamide is not indicated for use in women.
- **Fertility warning:** In men, this medicine 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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