

Darolutamide (Nubeqa®)

About This Drug

Darolutamide 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.
- Tiredness
- Changes in your liver function
- Pain in your leg, hand, arm and/or foot
- Rash

Note: Each of the side effects above was reported in 2% or greater of patients treated with darolutamide. Not all possible side effects are included above.

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 Medication

- 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. If you miss a dose, contact your doctor.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- 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. 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 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

- 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.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- 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 Drug Interactions

- This drug 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 dietary supplements you are taking before starting this medicine as there are known drug 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.
- Avoid the use of St. John's Wort while taking darolutamide as this may lower the levels of the drug 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
- Tiredness that interferes with your daily activities
- Signs of possible liver problems: dark urine, pale bowel movements, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Pain that does not go away, or is not relieved by prescribed medicines
- A new rash or a rash that is not relieved by prescribed medicines
- If you think you may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 1 week after your cancer treatment. 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. Darolutamide should never be used by 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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