Darolutamide (Nubeqa®)

Pronounced: dar-oh-loo-ta-mide

Classification: Anti-androgen

About Darolutamide (Nubeqa®)

Most prostate cancers need the male hormone testosterone to grow. Testosterone is an androgen (type of hormone) produced by the testes and adrenal glands. Darolutamide is an anti-androgen medication. Anti-androgen therapies work by blocking an enzyme necessary for the production of testosterone. Without testosterone, the cancer cells may either grow more slowly, or stop growing altogether.

How to Take Darolutamide

Darolutamide comes in tablet form, to be taken with food. The dose and how often you take this medication will be decided by your healthcare provider. Swallow the tablets whole. Do not crush or chew them. If you miss a dose of darolutamide, take your prescribed dose as soon as you remember before the next scheduled dose. Do not take 2 doses at once to make up for a missed dose.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

Certain medications and supplements, including but not limited to: carbamazepine, conivaptan, indinavir, itraconazole, ketoconazole, phenytoin, posaconazole, rifampin, ritonavir, St. John’s wort and telithromycin, can interfere with how darolutamide works, so be sure to tell your healthcare team about all medications, vitamins and supplements you are taking.

If you have not had a bilateral orchiectomy (removal of both testicles) this medication should be given with a gonadotropin-releasing hormone analog like leuprolide (Lupron®), gosarelin (Zoladex®) or triptorelin (Trelstar®)."

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Certain cancer medications are only available through specialty pharmacies. If you need to get this medication through a specialty pharmacy, your provider will help you start this process. Where you can fill your prescriptions may also be influenced by your prescription drug coverage. Ask your health care provider or pharmacist for assistance in identifying where you can get this medication.

Insurance Information
This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

**Possible Side Effects of Darolutamide**

There are a number of things you can do to manage the side effects of darolutamide. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**Liver Toxicity**

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

**Low White Blood Cell Count (Leukopenia or Neutropenia)**

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn’t heal.

Tips to preventing infection:

- **Washing hands**, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent **mouth care**.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

**Fatigue**

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Less common, but important side effects can include:

- **Seizures**: A seizure is caused by abnormal electrical activity in the brain and can lead to uncontrollable shaking of the body, loss of consciousness, and convulsions. The length and severity of the seizure may vary. If you are experiencing a seizure have someone call 911.
- **Ischemic heart disease**: Some patients taking this medication have experience heart blockages (ischemic heart disease). Your team will monitor your heart functions throughout treatment. Contact your care team or go to the emergency room if you have chest pain/discomfort or shortness of breath.

**Sexual and Reproductive Changes**

This drug can affect your reproductive system, resulting in sperm production becoming irregular or stopping permanently. In addition, you may experience erectile dysfunction or a decreased desire for sex during treatment. Talk to your urologist about options for treating erectile dysfunction.
Exposure of an unborn child to this medication could cause birth defects, so you should not father a child while on this medication. Effective birth control is necessary during treatment, and for 1 week after the last dose of darolutamide, even if you believe you are not producing sperm. You may want to consider sperm banking if you may wish to have a child in the future. Discuss these options with your oncology team.