

ORAL CANCER TREATMENT EDUCATION



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DAROLUTAMIDE

Name of your medication

Generic name — Darolutamide (DAR-oh-LOO-tuh-mide)
Brand name — Nubeqa® (NOO-bə-kə)

Common uses

Darolutamide is used to treat men with prostate cancer.
Darolutamide may also be used for other treatments.

Dose and schedule

Taking darolutamide as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of darolutamide is 600 milligrams (600 mg) to be taken by mouth at a scheduled time twice a day.
- Darolutamide should be taken with food, at the same times each day.
- Darolutamide should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow darolutamide, talk to your care provider or pharmacist for possible options.
- If you miss or vomit a dose of darolutamide, follow these guidelines:
 - Take it as soon as you remember, unless your next scheduled dose is due within 6 hours. Take the next dose at your regular time.
 - Do not take 2 doses at one time.
 - Be sure to write down if you miss a dose, and let your care provider know about any missed doses.

Drug and food interactions

- Darolutamide has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Grapefruit or grapefruit juice may interact with darolutamide; avoid eating or drinking this during treatment with darolutamide.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle darolutamide with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store darolutamide at room temperature (68°F–77°F) in a dry location away from light.
- Keep darolutamide out of reach of children and pets.

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- Leave darolutamide in the provided packaging until it is ready to be taken.
- Whenever possible, you should give darolutamide to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the darolutamide to you, they also need to follow these steps.
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the darolutamide from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- A daily pill box is not recommended to be used with darolutamide.
- If you have any unused darolutamide, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of darolutamide.
- If you are traveling, put your darolutamide's packaging in a separate sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Side Effects of Darolutamide

Below are common side effects that have been known to happen in about one-third or more of patients taking darolutamide; these are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Changes in liver function	Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following. <ul style="list-style-type: none">• Yellowing of the skin or whites of your eyes• Dark or brown urine• Bleeding or bruising

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Possible Side Effect	Management
Decreased white blood cells (WBCs) and increased risk for infection	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none">• Wash your hands often, especially before eating and after using the bathroom.• Avoid crowds and people with fevers, flu, or other infection.• Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection:</p> <ul style="list-style-type: none">• Fever (temperature more than 100.4°F or 38°C)• Chills• Sore throat• Burning with urination• Unusual tiredness• A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>

Serious side effects

- Darolutamide may cause narrowing of arteries in your heart. Contact your care team if you have shortness of breath or chest pain.
- If you have a history of seizures, darolutamide may make it more likely that you have a seizure. Seek medical attention right away if you have symptoms of a seizure.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since darolutamide remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take darolutamide, it is important to adhere to the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.

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- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or darolutamide with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking darolutamide. Males and females of childbearing age and potential should use effective contraception during therapy and for a minimum of 1 week after the last dose of darolutamide.
- Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care team for assistance.
- Darolutamide can cause serious birth defects and loss of pregnancy. Do not take darolutamide if you are pregnant or think you might be pregnant.

Obtaining medication

- Talk with your care provider about the process for obtaining your darolutamide.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

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Additional resources

Product website: <https://www.nubeqa-us.com>

Product prescribing information: https://labeling.bayerhealthcare.com/html/products/pi/Nubeqa_Pi.pdf?inline=

Product resources: <https://www.nubeqahcp.com/access-and-support>

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Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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