

Medication Information Sheet

darolutamide (DAR-oh-LOO-ta-mide)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Nubeqa®

Appearance: tablet

What is this medication for?

- For treating certain types of prostate cancer

What should I do before I have this medication?

Tell your health care team if you have or had significant medical condition(s), especially if you have / had:

- high blood pressure, diabetes, or high levels of fat in your blood,
- seizures,
- liver, kidney problems, or
- any allergies.

Darolutamide tablets contain a small amount of lactose. If you cannot have lactose, talk to your healthcare team.

Remember to:

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

How will this medication affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this medication may affect your sexual health.
- How this medication may affect your ability to have a baby, if this applies to you.

This medication may harm an unborn baby. While this may not be directly applicable to you:

- If there is any chance of pregnancy happening, you and your partner together must use 2 effective forms of birth control at the same time until **3 months** after your last treatment dose. Talk to your health care team about which birth control options are best for you.
- Do not donate sperm while using darolutamide and for **3 months** after your last dose.

How is this medication given?

- This medication is usually taken twice a day by mouth. Talk to your health care team about how and when to take your medication.
- Take the doses at about the same time each day.
- Swallow your tablet(s) whole. Take them with a full glass of water either during or just after a meal.
- If you miss a dose, take it as soon as possible. If it is close to your next dose, do not double the dose. Talk to your health care team.
- If you vomit (throw up) after taking your medication, talk to your health care team about what to do.
- Darolutamide is usually taken with another medication known as a gonadotropin-releasing hormone (GnRH) analogue, unless you had a surgery to remove your testicles in order to lower the amount of testosterone in your body. Your health care team will tell you exactly how to take darolutamide and the GnRH analogue and also when you should take them.
- If you take too much of your medication by accident, or if you think a child or a pet may have swallowed your medication, you must call the Ontario Poison Control Center right away at: 1-800-268-9017.

What else do I need to know while on this medication?

Will this medication interact with other medications or natural health products?

- This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment not work as well or cause severe side effects.
- Tell your health care team about all of your:
 - ◊ prescription and over-the-counter (non-prescription) medications and all other drugs, such as marijuana (medical or recreational)
 - ◊ natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
- Check with your health care team before starting or stopping any of them.

What to DO while on this medication:

- DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.

What NOT to DO while on this medication:

- DO NOT smoke or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.

How should I safely store this medication?

- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.

How to safely touch oral anti-cancer medications

If you are a patient:

- Wash your hands before and after touching your oral anti-cancer medication.
- Swallow each pill whole. Do not crush or chew your pills.

If you are a caregiver:

- Wear nitrile or latex gloves when touching tablets, capsules or liquids.
- Wash your hands before putting on your gloves and after taking them off, even if your skin did not touch the oral anti-cancer medication.
- Throw out your gloves after each use. Do not re-use gloves.
- Do not touch oral anti-cancer medications if you are pregnant or breastfeeding.

What to do if oral anti-cancer medication gets on your skin or in your eyes

If medication gets on your skin:

- Wash your skin with a lot of soap and water.
- If your skin gets red or irritated, talk to your health care team.

If medication gets in your eyes:

- Rinse your eyes with running water right away. Keep water flowing over your open eyes for at least 15 minutes.

What are the side effects of this medication?

The following table lists side effects that you may have when getting darolutamide. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on darolutamide.

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Liver problems</p> <p>(May be severe)</p> <p>Your health care team may check your liver function with a blood test. The liver changes do not usually cause any symptoms.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe. <p>What to do?</p> <p>If you have any symptoms of liver problems, get emergency medical help right away.</p>	<p>Get emergency medical help right away</p>
<p>Fatigue</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. <p>What to do?</p> <ul style="list-style-type: none"> • Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. • Check with your health care team before starting any new exercise. • Pace yourself, do not rush. Put off less important activities. Rest when you need to. 	<p>Talk to your health care team if it does not improve or if it is severe</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> • Ask family or friends to help you with things like housework, shopping, and child or pet care. • Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). • Avoid driving or using machinery if you are feeling tired. <p>Ask your health care team for the Fatigue pamphlet for more information.</p>	

Other rare, but serious side effects are possible.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- irregular heartbeat, chest pain or fainting spells
- extreme tiredness, swelling in your legs, ankles and belly
- coughing, breathing problems, pain in your chest or coughing up blood
- seizures
- severe or unusual bone pain especially in your back, hips or wrists
- changes in peeing such as less urine than usual, trouble with peeing or blood in your pee

Who do I contact if I have questions or need help?

My cancer health care provider is: _____

During the day I should contact: _____

Evenings, weekends and holidays: _____

Other Notes:

March 2024 Updated “How will this medication affect sex, pregnancy and breastfeeding?” section

For more links on how to manage your symptoms go to www.cancercareontario.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.