



WHAT IS NUBEQA® DAROLUTAMIDE?

- An antihormone therapy drug used to treat some prostate cancers.
- Prescribed by your hospital-based oncologist or cancer specialist at least one per year; can be renewed by your registered physician.
- Available from community pharmacies on presentation of your prescription.




- Oval, white, film-coated tablet dosed at **300 mg**, with "300" on one side and "BAYER" on the other.



- Do not store above 30°C and keep out of the sight and reach of children.
- Do not take the tablets out of the box to put them in a pillbox.
- Wash your hands carefully before and after handling the tablets.
- Do not throw away opened boxes, please return them to your pharmacist.

HOW TO TAKE THIS MEDICINE

When?:..... and:.....	= 2 doses per day at a set time With a meal
How?		Swallow the tablets with water at the same time every day. Do not chew, cut, crush or dissolve them.

You can use your **patient diary*** and a **calendar** to note doses.

Do not stop taking or change how you take your treatment without consulting your doctor.

This leaflet is not a prescription, please refer to your most recent prescription.

IF YOU FORGET TO TAKE YOUR MEDICINE OR VOMIT

- **If you forget to take your medicine**, take the missed dose as soon as possible before the next scheduled dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your patient diary*.
- **If you throw up**, do not take another dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your patient diary*.



INTERACTION WITH OTHER MEDICINES AND OTHER INTERACTIONS



Check with **your doctor or pharmacist** that the medicines (prescribed or over-the-counter), other substances (foods, spices and plants, including **grapefruit** and **St. John's Wort**, probiotics, essential oils, food supplements, etc.) and derivative products you use are **compatible with your treatment**. The molecules they contain, their dose and how often they are taken can interact with your treatment and affect effectiveness and the occurrence of side effects.











- If you have sexual intercourse with a woman of child-bearing age or who is pregnant, you must use highly effective methods of contraception (condoms and another method) throughout treatment **and for 1 week after the last dose**.

* Patient diary available (in French) at www.omedit-fiches-cancer.fr

WHAT SIDE EFFECTS CAN OCCUR WITH NUBEQA® DAROLUTAMIDE?

Like all medicines, darolutamide may cause side effects, although not everybody gets them.

Side effects	Prevention
 Rash	Use soap-free gel or a dermatological bar. Avoid hot water. Pat dry. Use moisturiser (cream or milk). Avoid sun exposure, particularly between noon and 4pm. Wear protective clothing, even under a parasol (UVA reflection). Use SPF 50+ sun cream, applied 30 minutes before exposure and reapplied every 2 hours.
 Joint and muscle pain	Exercise regularly (suitable activities include walking and swimming). Warm up before exercising. Remember to hydrate before, during and after exerting yourself. Avoid repetitive movements and strenuous physical effort. Use a walking stick to support your joints.
 Tiredness	Eat a balanced diet. Avoid using psychostimulants (e.g. coffee, tobacco, alcohol). Take care when driving. Rest during the day, while maintaining up to moderate levels of activity. Go to bed at a regular time and get sufficient sleep at night.
 Palpitations	Reduce stimulants (tea, coffee, alcohol, tobacco). Get enough sleep on a regular schedule. Practice relaxation techniques (sophrology, yoga, tai chi). Measure your heart rate (heart rate monitor, smartwatch or manually); keep a record. Contact your doctor if you experience malaise, dizziness, difficulty breathing or chest pain.
 High blood pressure	Headaches, dizziness, and tinnitus are the first warning signs of high blood pressure. Measure your blood pressure (resting and sitting down, in the morning before breakfast and in the evening before going to bed; take three measurements two minutes apart); keep a record of your results. Exercise regularly (suitable activities) (30 minutes 3 times per week). Limit salt (max. 5 g per day) and alcohol. Eat a diet low in saturated fats (animal fats) and high in fibre.
 Low white blood cells	Contact your doctor in case of temperature > 38°C, chills, sweating, cough, shortness of breath/pain when breathing, a burning sensation when urinating, diarrhoea accompanied by fever or any other signs suggesting infection.
 Swelling of the face or limbs	Eat a diet low in salt. Avoid tight clothing. If your legs swell, raise your feet when sitting. Wear compression stockings; put them on when getting up in the morning. Weigh yourself regularly. Consult your doctor if this type of swelling occurs.
	<p>Only the most common side effects are listed here. For more information, read the Patient Leaflet included with your medicine or ask your doctor or pharmacist.</p> <p>You can also ask your Regional Pharmacovigilance Centre and report any side effects online: signalement-sante-gouv-fr</p>



Remember to go for the lab tests prescribed by your doctor.

WHAT TO DO IF YOU EXPERIENCE SIDE EFFECTS

- Take the medicine prescribed to counteract the side effects, as prescribed.
- Follow the preventive measures.

Useful contacts:

Contact your doctor rapidly in case of:

- Chest pain, palpitations
- Signs of infection (fever, cough, chills, burning sensation when urinating, etc.)
- Any persistent or worsening side effect



Note: