

Package leaflet: Information for the patient

NUBEQA 300 mg film-coated tablets darolutamide

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What NUBEQA is and what it is used for
2. What you need to know before you take NUBEQA
3. How to take NUBEQA
4. Possible side effects
5. How to store NUBEQA
6. Contents of the pack and other information

1. What NUBEQA is and what it is used for

NUBEQA contains the active substance darolutamide.

It is used to treat **adult men with prostate cancer** that:

- has not spread to other parts of the body and no longer responds to medical or surgical treatment that lowers testosterone (also called non-metastatic castration-resistant prostate cancer)
- has spread to other parts of the body and responds to medical or surgical treatment that lowers testosterone (also called metastatic hormone-sensitive prostate cancer).

How NUBEQA works

NUBEQA blocks the activity of male sex hormones called androgens, such as testosterone. By blocking these hormones, darolutamide stops prostate cancer cells from growing and dividing.

2. What you need to know before you take NUBEQA

Do not take NUBEQA if

- you are allergic to darolutamide or any of the other ingredients of this medicine (listed in section 6)
- you are a woman who is or may become pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before taking NUBEQA if

- you have problems with your kidneys
- you have problems with your liver

- you have any heart conditions including heart rhythm problems or if you are using medicines for these conditions
- you had a surgery to treat blood vessel conditions.

Taking this medicine may affect your liver tests. If your blood tests show abnormal results of your liver function, your doctor may decide to stop treatment permanently.

Children and adolescents

This medicine is not for use in children and adolescents under 18 years. Prostate cancer does not occur in this age group.

Other medicines and NUBEQA

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines may influence the effect of NUBEQA, or NUBEQA may influence the effect of these medicines to treat:

- bacterial infections, such as **rifampicin**
- epilepsy, such as **carbamazepine, phenobarbital, phenytoin**
- symptoms of slightly low mood and mild anxiety: **St. John's wort** (a herbal medicine)
- high cholesterol, such as **rosuvastatin, fluvastatin, atorvastatin, pitavastatin**
- severe joint inflammation, severe cases of the skin disease psoriasis, and cancers: **methotrexate**
- inflammatory bowel diseases: **sulfasalazine**

Your doctor may therefore change the dose of the medicines that you are taking.

Pregnancy, breast-feeding and fertility

NUBEQA is not for use in women.

This medicine could possibly have an effect on male fertility.

Follow these advices during and for 1 week after stopping:

- use a highly effective method of contraception to prevent pregnancy, if you are having sex with a woman who can become pregnant.
- use a condom to protect the unborn baby, if you are having sex with a pregnant woman.

Driving and using machines

This medicine is unlikely to affect your ability to drive and use machines.

NUBEQA contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take NUBEQA

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is

2 tablets 2 times daily

Your doctor may reduce your dose to 1 tablet 2 times daily, if you have problems with your liver or kidneys.

Method of use

Swallow the tablets whole, take them with food and a glass of water.

Your doctor may also prescribe other medicines while you are taking NUBEQA.

If you take more NUBEQA than you should

Continue the treatment with the next dose as scheduled.

If you forget to take NUBEQA

Take your missed dose as soon as you remember before the next scheduled dose. Do not take a double dose to make up for 1 or more forgotten tablets.

If you stop taking NUBEQA

Do not stop taking this medicine unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects of NUBEQA occur with the following frequencies:

In patients with non-metastatic castration-resistant prostate cancer

Very common side effects (may affect more than 1 in 10 people):

- tiredness
- blood tests showing reduced number of a white blood cell type called neutrophils
- blood tests showing increased levels of substances produced by the liver: bilirubin, aspartate transaminase

Common side effects (may affect up to 1 in 10 people):

- blockage of the arteries in the heart
- heart failure
- rash
- pain in arms and legs
- pain in muscles and bones
- broken bones

In patients with metastatic hormone-sensitive prostate cancer

Very common side effects (may affect more than 1 in 10 people):

- high blood pressure
- rash
- blood tests showing reduced number of a white blood cell type called neutrophils
- blood tests showing increased levels of substances produced by the liver: bilirubin, alanine transaminase and aspartate transaminase

Common side effects (may affect up to 1 in 10 people):

- broken bones
- breast enlargement in men

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

To report any side effect(s):	
Kuwait: Drug & Food Control, Ministry of Health ,Kuwait Tel.: +965-24811532 Fax: +965-24811507 Email : Adr_reporting@moh.gov.kw Website: http://eservices.moh.gov.kw/SPCMS/DrugCmp.aspx	Saudi Arabia: The National Pharmacovigilance Centre (NPC). SFDA Call Center: 19999 E-mail: npc.drug@sfda.gov.sa Website: https://ade.sfda.gov.sa
United Arab Emirates (UAE): Pharmacovigilance & Medical Device section Tel: 800111111 / +971 42301000 Email: pv@mohap.gov.ae Website: www.mohap.gov.ae P.O.Box 1853 Dubai	Egypt: Egyptian Pharmaceutical Vigilance Centre Hotline: 15301 Email: pv.followup@edaegypt.gov.eg Website: www.edaegypt.gov.eg
Oman: Tel: +968 - 2444 1999 Fax: +968 - 24602287 Email: pharma-vigil@moh.gov.om Website: www.moh.gov.om	Jordan: Tel +:962-6-5632000 JFDA email : jpc@jfda.jo JFDA website: www.jfda.jo http://primaryreporting.who-umc.org/JO
Other Countries: Please contact the relevant competent authority	

5. How to store NUBEQA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on each blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What NUBEQA contains

The active substance is darolutamide. Each film-coated tablet contains 300 mg of darolutamide.

The other ingredients are:

- calcium hydrogen phosphate (E 341)
- croscarmellose sodium
- hypromellose
- lactose monohydrate
- macrogol (E 1521)
- magnesium stearate (E 470b)
- povidone (E 1201)
- titanium dioxide (E 171)

See “NUBEQA contains lactose” in section 2 for more information.

What NUBEQA looks like and contents of the pack

The film-coated tablets (tablets) are white to off-white, oval with a length of 16 mm and a width of 8 mm. They are marked with “300” on one side, and “BAYER” on the other side.

Each carton contains 112 film-coated tablets consisting of 7 blisters
Each blister contains 16 film-coated tablets.

Bulk Manufacturer:

Orion Corporation, Orion Pharma
Orionintie 1
02200 Espoo, Finland

Packaging and Batch release site:

Orion Corporation, Orion Pharma
Joensuunkatu 7
24100 Salo, Finland

Marketing Authorisation Holder:

Bayer AG,
51368 Leverkusen, Germany.

This leaflet was last revised in February 2023

This is a medicinal product

- A medicine is a product which affects your health and can harm you if taken contrary to directions
- Keep strictly to your doctor’s instructions, the instructions for use and the instructions of the pharmacist who sold you this medicine. Your doctor and pharmacist are experts on medicine and its benefits and risks
- Do not stop taking this medicine before the end of the prescribed course of treatment
- Do not use this medicine on another occasion without consulting your doctor

Keep medicines out of the reach of children

**Council of Arab Health Ministers
Union of Arab Pharmacists**