

NUBEQA® 300 mg film-coated tablets

(darolutamide)

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.

The name of your medicine is “NUBEQA® 300 mg film-coated tablets”, but will be referred to as “NUBEQA” in this leaflet.

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) or
- 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). For this, your doctor may also give you docetaxel.

How NUBEQA works

NUBEQA blocks the activity of male sex hormones called androgens, such as testosterone. Androgens can cause the prostate cancer to grow. 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 ever had seizures
- you have problems with your kidneys
- you have problems with your liver
- you have narrowing of arteries in the heart, or 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
- if you have high blood pressure.

Taking this medicine may affect your liver function. If your blood tests show abnormal results of your liver function, your doctor may decide that you stop taking NUBEQA 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.

These medicines are typically used to treat:

- bacterial infections, such as **rifampicin**
- epilepsy, such as **carbamazepine, phenobarbital, phenytoin**
- 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 reduce male fertility. Follow these advices during and for 1 week after stopping:

- use a condom or another highly effective method of birth control to prevent pregnancy, if you are having sex with a woman who can become pregnant. Ask your doctor about the best method of birth control for you.
- 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. Do not take more than 4 tablets per day.

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 – do not split or crush them. Take the tablets 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.

You should **immediately contact your doctor** if you experience any of the following **serious side effects**:

- Chest pain, pain in other parts of the body (spreading from your chest to your arms, jaw, neck, back and tummy), feeling lightheaded or dizzy, sweating, shortness of breath, feeling sick (signs of heart disease caused by blockage of the blood vessels in the heart).
- Breathlessness after activity or at rest, tiredness most of the time, feeling lightheaded or fainting and swelling of the ankles and legs (signs of heart failure).
- Seizures

Please contact your doctor if symptoms that are occasionally related to signs of liver injury like, feeling sick (nausea), vomiting, abdominal discomfort or loss of appetite persist, yellowing of the skin or eyes and darkening of the urine occur.

Side effects of NUBEQA occur with the following frequencies:

In patients with non-metastatic castration-resistant prostate cancer and metastatic hormone-sensitive 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, alanine transaminase and aspartate transaminase
- blood tests showing reduced number of red blood cells

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

- rash
- pain in arms and legs
- broken bones

In patients with metastatic hormone-sensitive prostate cancer when used in combination with docetaxel

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

- high blood pressure
- rash
- blood tests showing increased levels of substances produced by the liver: bilirubin, alanine aminotransferase and aspartate transaminase

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.

You can also report side effects directly via the Yellow Card Scheme Website:

https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

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.

This medicine does not require any special storage conditions.

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.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

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 with 16 film-coated tablets.

Manufacturer

Orion Corporation, Orion Pharma
24100 Salo
Finland

Procured from within the EU and repackaged for the PL Holder: Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom

NUBEQA® 300 mg film-coated tablets
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