PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NUBEQA 300 mg film-coated tablets
Darolutamide
Contains sugar (lactose monohydrate 180 mg)

Read all of this leaflet carefully before you start NUBEQA
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- NUBEQA has been prescribed for you personally and you should not share your medicines with other people. It may harm them, even if their symptoms are the same as yours.

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
Always tell your health care provider if you are taking any other medicines. This includes all complementary or traditional 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, phenobarbitone, 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

Do not share medicines prescribed for you with any other person.
Always take NUBEQA 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

NUBEQA can have side effects.

Not all side effects reported for NUBEQA are included in this leaflet. Should your general health worsen or if you experience any untowrd effects while taking NUBEQA, please consult your health care porvider for advice.

Side effects of NUBEQA occur with the following frequencies:

In patients with non-metastatic castration-resistant prostate cancer
Frequent side effects:
- 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
- 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
Frequent side effects:
- 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

- broken bones
- breast enlargement in men

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Alternatively, you can report to Bayer SafeTrack site (https://www.safetrack-public.bayer.com). By reporting side effects, you can help provide more information on the safety of NUBEQA.

5. How to store NUBEQA

Keep this medicine out of the sight and reach of children.
Store at or below 30 °C.

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 dispose of unused medicine in drains or sewerage systems (e.g. toilets). 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 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.

Holder of Certificate of Registration
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This leaflet was last revised in
6 December 2024

Registration number
55/21.12/0321

Botswana: (S2) BOT2304028
Namibia: NS2 23/21.12/0048
Manufacturered by Orion Corporation, Orion Pharma, Espoo, Finland