PATIENT INFORMATION
NUBEQA® (NOO-bə-kə**)**
(darolutamide)
tablets

What is NUBEQA?

NUBEQA is a prescription medicine used to treat adults with prostate cancer:

- that has not spread to other parts of the body and no longer responds to a medical or surgical treatment that lowers testosterone
- that has spread to other parts of the body and responds to a medical or surgical treatment that lowers testosterone
- that has spread to other parts of the body and responds to a medical or surgical treatment that lowers testosterone in combination with docetaxel.

It is not known if NUBEQA is safe and effective in females or children.

Before taking NUBEQA, tell your healthcare provider about all your medical conditions, including if you:

- have heart problems
- have high blood pressure
- have diabetes
- have high amounts of fat or cholesterol in your blood (dyslipidemia)
- have a history of seizures, brain injury, stroke, or brain tumors
- have kidney or liver problems
- are pregnant or plan to become pregnant. NUBEQA can cause harm to your unborn baby and loss of pregnancy (miscarriage).
- have a partner who may become pregnant. Males who have female partners who may become pregnant should use effective birth control (contraception) during treatment and for 1 week after the last dose of NUBEQA. Talk with your healthcare provider about birth control methods.
- are breastfeeding or plan to breastfeed. It is not known if NUBEQA passes into breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. NUBEQA may affect the way other medicines work and other medicines may affect how NUBEQA works.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed NUBEQA.

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take NUBEQA?

- Take NUBEQA exactly as your healthcare provider tells you.
- Your healthcare provider may change your dose, temporarily stop, or completely stop your treatment with NUBEQA if you have certain side effects.
- Take your prescribed dose of NUBEQA 2 times a day with food.
- Swallow NUBEQA tablets whole.
- If you are receiving gonadotropin-releasing hormone (GnRH) therapy, you should continue with this treatment during your treatment with NUBEQA unless you have had a surgery to lower the amount of testosterone in your body (surgical castration).
- If you miss a dose of NUBEQA, take the missed dose as soon as you remember. If it is time for your next scheduled dose, you may take the missed dose together with your next scheduled dose. Then go back to your regular schedule taking NUBEQA 2 times a day.
- If you take more NUBEQA than prescribed, call your healthcare provider right away.

What are the possible side effects of NUBEQA?

NUBEQA may cause serious side effects, including:

- **Heart disease.** Blockage of the arteries in the heart (ischemic heart disease) that can lead to death has happened in some people during treatment with NUBEQA. Your healthcare provider will monitor you for signs and symptoms of heart problems during your treatment with NUBEQA. Call your healthcare provider or get medical help right away if you get chest pain or discomfort at rest or with activity, or shortness of breath during your treatment with NUBEQA.
- **Seizure.** Treatment with NUBEQA may increase your risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have loss of consciousness or seizure during treatment with NUBEQA.

The most common side effects of NUBEQA include:

- increase in liver function tests
- decreased white blood cells (neutropenia)
- feeling more tired than usual

The most common side effects of NUBEQA in combination with docetaxel include:

- constipation
- rash
- decreased appetite
- bleeding
- weight gain
- high blood pressure
- decreased red blood cells (anemia)
- high blood sugar levels
- decreased white blood cells
- increase in liver function tests
- low blood calcium levels

NUBEQA may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility.
These are not all the possible side effects of NUBEQA.
Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NUBEQA?

- Store NUBEQA at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the bottle tightly closed after you first open it.

Keep NUBEQA and all medicines out of the reach of children.

General information about the safe and effective use of NUBEQA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use NUBEQA for a condition for which it was not prescribed. Do not give NUBEQA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about NUBEQA that is written for health professionals.

What are the ingredients in NUBEQA?

Active ingredient: darolutamide

Inactive ingredients: calcium hydrogen phosphate, croscarmellose sodium, lactose monohydrate, magnesium stearate, povidone K 30, hypromellose 15 cP, macrogol 3350, and titanium dioxide.

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