

## PATIENT INFORMATION

NUBEQA® (NOO-bə-kə)

(darolutamide)

Tablets

### What is NUBEQA?

NUBEQA is a prescription medicine used to treat men 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.

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

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

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

- 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 if needed.
- Take your prescribed dose of NUBEQA 2 times a day with food.
- Swallow NUBEQA tablets whole.
- If you are receiving gonadotropin-releasing hormone (GnRH) analog 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 your prescribed dose as soon as you remember before the next scheduled dose. Do not take 2 doses together to make up for a missed dose.

### What are the possible side effects of NUBEQA?

**The most common side effects of NUBEQA include:**

- feeling more tired than usual
- arm, leg, hand or foot pain
- rash
- decreased white blood cells (neutropenia)
- changes in liver function tests

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.

**Manufactured by:** Orion Corporation, Orion Pharma, FI-02101 Espoo, Finland

**Manufactured for:** Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ 07981 USA

© 2019 Bayer HealthCare Pharmaceuticals Inc.

For more information, call Bayer HealthCare Pharmaceuticals Inc. at Bayer at 1-888-842-2937 or go to [www.NUBEQA-us.com](http://www.NUBEQA-us.com)