

SECOND FDA APPROVAL

Now for adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel



NUBEQA
is pronounced
new-BEH-kah

NUBEQA HELPS YOU LIVE FOR WHAT YOU LOVE

The clinical study for NUBEQA was designed to measure overall survival (OS). NUBEQA extended OS by lowering the risk of death by 32% compared with chemotherapy* + hormone therapy† alone.

*Docetaxel.

†Hormone therapy includes gonadotropin-releasing hormone (GnRH), such as Lupron Depot® (drug treatment), or surgery that lowers testosterone.

WHAT IS NUBEQA®?

NUBEQA® (darolutamide) is a prescription medicine used to treat adults with prostate cancer that has spread to other parts of the body and responds to medical or surgical treatment that lowers testosterone (mHSPC), in combination with docetaxel.

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

IMPORTANT SAFETY INFORMATION

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

- have heart problems, high blood pressure, diabetes, or high amounts of fat or cholesterol in your blood (dyslipidemia)
- have a history of seizures, brain injury, stroke, or brain tumors

Please see additional Important Safety Information throughout and the full [Prescribing Information](#).



NUBEQA®
(darolutamide) 300 mg
tablets



NUBEQA

The **first and only** treatment of its kind approved for mHSPC in combination with docetaxel

mHSPC=metastatic hormone-sensitive prostate cancer.

See overall survival data and other clinical study results on page 6.

Whether you've already started NUBEQA,
or you're thinking about it

THIS BROCHURE IS FOR YOU

TAKING ACTION

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IMPORTANT SAFETY INFORMATION (cont'd)

Before taking NUBEQA, tell your healthcare provider about all your medical conditions, including if you: (cont'd)

- 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

Please see additional Important Safety Information throughout and the full [Prescribing Information](#).

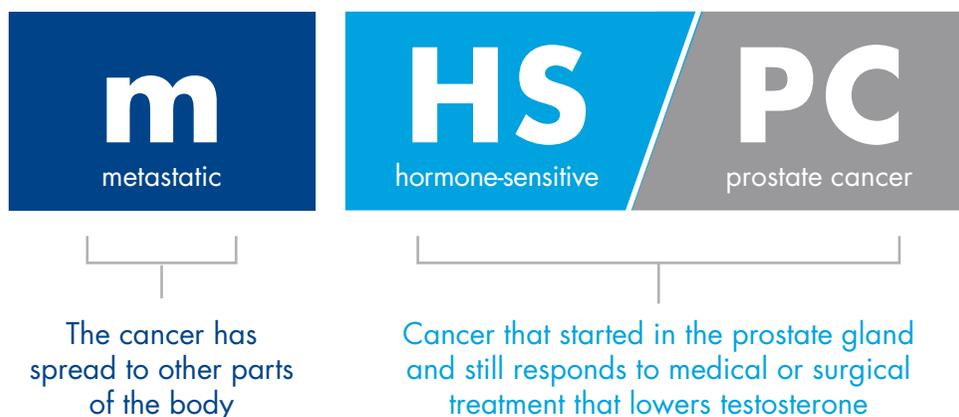


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WHEN PROSTATE CANCER HAS SPREAD TO OTHER PARTS OF THE BODY

At this point, you and your doctor may have done a number of tests to learn more about the prostate cancer in your body. When the tests show that prostate cancer has spread to other parts of the body, it is called **metastatic**. It is important to know if your prostate cancer has spread, because your doctor may consider a different approach than the one used to treat prostate cancer that has not spread.

WHAT IS mHSPC?



IMPORTANT SAFETY INFORMATION (cont'd)

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.

A NEW FDA-APPROVED APPROACH FOR TREATING mHSPC

THE NUBEQA COMBINATION NOW YOU CAN FIGHT mHSPC 3 WAYS AT ONCE



NUBEQA is a pill for prostate cancer that blocks testosterone, which helps delay cancer cell growth. NUBEQA is a type of medicine called an **androgen receptor inhibitor**, or **ARI**.



Docetaxel (pronounced doe-suh-TAK-sel) is a chemotherapy that helps stop the growth and spread of cancer cells. Docetaxel is only given for approximately 4 months at the start of treatment with NUBEQA.



Hormone therapy helps lower **testosterone** levels so that prostate cancer does not continue growing or spreading. Hormone therapy may refer to an **androgen deprivation therapy (ADT)**, such as Lupron Depot[®], or may refer to a surgical treatment called an orchiectomy.

mHSPC=metastatic hormone-sensitive prostate cancer.
Lupron Depot is a registered trademark of AbbVie Inc.

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CLINICALLY PROVEN TO HELP MEN LIVE LONGER

SUCCESSFUL RESULTS IN A CLINICAL TRIAL OF 1305 MEN WITH mHSPC

- 651 men received the NUBEQA combination
 - Patients who were given the NUBEQA combination in the clinical trial received chemotherapy* for 6 cycles (approximately 4 months) and continued receiving NUBEQA and hormone therapy† until their doctor stopped their treatment
- 654 men received chemotherapy* + hormone therapy† alone
 - Patients received chemotherapy* for 6 cycles (approximately 4 months) and continued receiving hormone therapy† until their doctor stopped their treatment

The study measured **overall survival (OS)**, which is the length of time a person may live after starting therapy. The study also measured the length of time before disease progressed to mCRPC‡ and the length of time before pain progressed.

*Docetaxel.

†Hormone therapy includes gonadotropin-releasing hormone (GnRH), such as Lupron Depot® (drug treatment), or surgery that lowers testosterone.

‡mCRPC=metastatic castration-resistant prostate cancer, which is prostate cancer that has spread to other parts of the body and no longer responds to hormone therapy.

mHSPC=metastatic hormone-sensitive prostate cancer.

IMPORTANT SAFETY INFORMATION (cont'd)

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

NUBEQA HELPS YOU LIVE FOR WHAT YOU LOVE

AT 4 YEARS OF TREATMENT IN THE CLINICAL STUDY

MEN LIVED LONGER WITH NUBEQA

More men who received the NUBEQA combination were still alive (63% compared with 50% of the men who received chemotherapy* + hormone therapy†)

- The NUBEQA combination extended OS by lowering the risk of death by 32%

MORE TIME WITHOUT PAIN PROGRESSION

- NUBEQA lowered the risk of time to pain progression by 21%

THE BOTTOM LINE

Chemotherapy* + hormone therapy† is a guideline-recommended treatment for mHSPC. Adding NUBEQA may help you live even longer.

Please see additional Important Safety Information throughout and the full [Prescribing Information](#).


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POSSIBLE SIDE EFFECTS WITH NUBEQA

NUBEQA may cause fertility problems in males, which may affect their ability to father children. Talk to your healthcare provider if you have concerns about fertility.

TALK TO YOUR DOCTOR ABOUT THE MEDICINES YOU ARE TAKING

Although NUBEQA has a limited potential to interfere with other medicines, it may interfere with some medicines you are taking. So be sure to tell your doctor about all the medicines you are taking, including over-the-counter medicines and supplements.

IMPORTANT SAFETY INFORMATION (cont'd)

The most common side effects of NUBEQA when used in combination with docetaxel in people with mHSPC include:

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

*Hormone therapy includes gonadotropin-releasing hormone (GnRH), such as Lupron Depot® (drug treatment), or surgery that lowers testosterone.



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HOW TO TAKE NUBEQA

FOLLOW YOUR DOCTOR'S INSTRUCTIONS WHILE TAKING NUBEQA

The recommended dose of NUBEQA is 600 mg (two 300 mg tablets) taken by mouth, twice daily



- Take NUBEQA with food
- Swallow NUBEQA tablets whole
- If you miss a dose of NUBEQA, take your normal dose as soon as possible prior to the next scheduled dose
 - **Return to your normal schedule on the following day. Do not take 2 doses together to make up for a missed dose**
- Your doctor may change your dose, temporarily stop, or completely stop your treatment with NUBEQA if you have certain side effects. Do not stop taking your prescribed dose of NUBEQA without talking with your doctor first
- If you take more NUBEQA than prescribed, call your healthcare provider right away

THE NUBEQA COMBINATION FIGHTS YOUR CANCER 3 WAYS AT ONCE



After chemotherapy† has concluded, continue taking NUBEQA + hormone therapy until your doctor tells you to stop

*Hormone therapy includes gonadotropin-releasing hormone (GnRH), such as Lupron Depot® (drug treatment), or surgery that lowers testosterone.

†Docetaxel.

HORMONE THERAPY* WILL BE ADMINISTERED BY YOUR DOCTOR

- You should continue hormone therapy during your treatment with NUBEQA unless you had surgery to lower the amount of testosterone in your body (surgical castration)
- Hormone therapy medications are given by injection or are implanted under the skin

YOUR DOCTOR WILL BEGIN CHEMOTHERAPY† WITHIN 6 WEEKS OF STARTING NUBEQA

A chemotherapy called docetaxel is given as an intravenous (IV) infusion in your arm.

- Docetaxel is given once every 21 days, or as recommended by your doctor
- A total of up to 6 treatments will be administered, lasting ~4 months
- Your doctor may change, delay, or stop treatment with docetaxel if needed

TIP

Set a reminder on your phone to remind you when to take NUBEQA

IMPORTANT SAFETY INFORMATION (cont'd)

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 the FDA at 1-800-FDA-1088.

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SUPPORT SERVICES FOR MEN TAKING NUBEQA

ACCESS SERVICES BY BAYER™ IS HERE TO HELP

with a range of services and resources to support you, including:



Assistance to help you understand your insurance benefits for NUBEQA



Access to a nurse who can answer treatment questions



Assistance with insurance coverage barriers



Connecting you with financial assistance to help pay for NUBEQA

To find out more about how these programs and other support services can help, call:

1-800-288-8374

MONDAY–FRIDAY: 9:00 AM–6:00 PM (ET)

 **Access Services**
by Bayer™

TIP

Save the Access Services by Bayer™ number in your phone so it doesn't appear as spam, and answer all calls from the program

ACCESS SERVICES BY BAYER™ IS HERE TO HELP FIND THE NUBEQA FINANCIAL ASSISTANCE THAT IS RIGHT FOR YOU



NUBEQA Free Trial Program

Patients who are **NEW** to NUBEQA can get 1 month of free medication*

NUBEQA \$0 Co-Pay Program—for eligible patients with insurance through an employer or insurance they have purchased themselves (also known as commercial or private insurance).†

Referrals to charitable foundations—may be able to help patients with government-sponsored insurance (such as Medicare, Medigap, Medicaid, VA/DoD health plans, and TRICARE) with out-of-pocket costs.

- Patient Access Specialists can verify your coverage for NUBEQA and provide information about any available foundations

Referral to Bayer US Patient Assistance Foundation—provides free medicine for patients who are uninsured or underinsured and meet certain eligibility criteria.‡

*The NUBEQA Free Trial Program provides 1 month's supply of NUBEQA at no cost to patients who meet the program eligibility requirements and agree to the terms and conditions. For full terms and conditions, please call Access Services by Bayer™ at 1-800-288-8374.

†Restrictions may apply. For full terms and conditions, please call Access Services by Bayer™ at 1-800-288-8374 or visit NUBEQAcopayprogram.com. Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. As a condition precedent of the co-payment support provided under this program, eg, co-pay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payers of any benefits they receive and the value of this program, as required by contract or otherwise. Void where prohibited by law, taxed, or restricted. Eligibility and participation are subject to review and may be modified or discontinued at any time.

‡Bayer provides NUBEQA free of charge for eligible patients who are uninsured or underinsured. In order to qualify for assistance, you must meet certain eligibility criteria.

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Learn more at [NUBEQA.com](https://www.nubeqa.com)

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