



**EVEN WITH RISING
PSA ON HORMONE
THERAPY***

NUBEQA HELPS YOU LIVE FOR WHAT YOU LOVE

NUBEQA clinical study was designed to measure metastasis-free survival (MFS) and also overall survival (OS). NUBEQA extended OS by lowering the risk of death by 31% compared with hormone therapy alone. See the clinical results on [page 8](#).

*Hormone therapy includes drug treatments or surgery that lowers testosterone.
PSA=prostate-specific antigen.

WHAT IS NUBEQA®?

NUBEQA® (darolutamide) 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 medical or surgical treatment that lowers testosterone (non-metastatic castration-resistant prostate cancer or nmCRPC).

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)

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

Pronounced new-BEH-kah



If hormone therapy* no longer controls your prostate cancer that has not spread to other parts of the body

TAKE ACTION

*Hormone therapy includes drug treatments or surgery that lowers testosterone.

IMPORTANT SAFETY INFORMATION (cont'd)

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

- have a history of seizures, brain injury, stroke, or brain tumors

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

THIS BROCHURE IS FOR YOU

TAKING ACTION

When you need more than your current hormone therapy*	4
Rising PSA levels mean that your cancer could spread.	5

CHOOSING NUBEQA

When it's time to take action, there's NUBEQA.	6
How NUBEQA works	7
NUBEQA is clinically proven	8
NUBEQA offers men other benefits	10
Possible side effects with NUBEQA	12
How to take NUBEQA.	14
Support services for men taking NUBEQA	16

MORE INFORMATION

For people who care for someone with prostate cancer	18
Where to find more information	19
My treatment team	20
What should you discuss with your doctor?	21
Glossary	22

TIP

Take notes on [page 23](#) at each visit with your doctor so you can refer to them later

Throughout the brochure, you'll see **bolded terms**. Flip to [page 22](#) of this brochure for a glossary of these terms.

*Hormone therapy includes drug treatments or surgery that lowers testosterone.

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

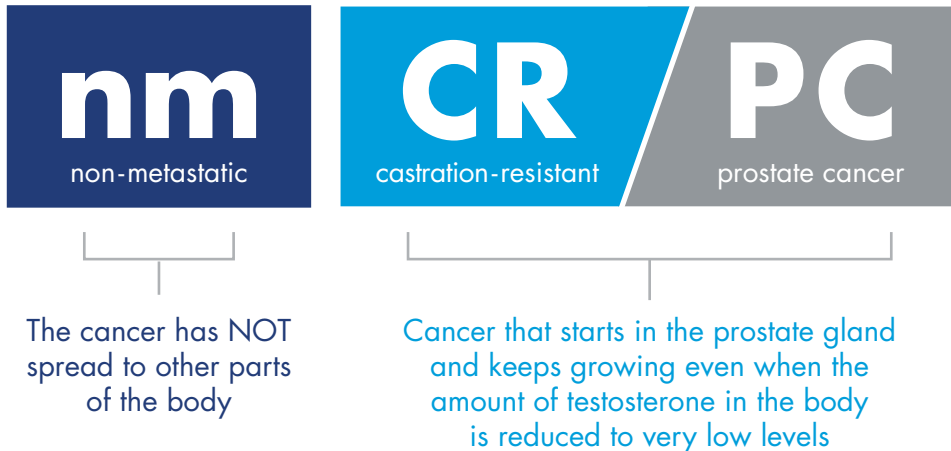
WHEN YOU NEED MORE THAN YOUR CURRENT HORMONE THERAPY*

When you have prostate cancer, the **testosterone** in your body causes it to grow and spread. You may already be on a **hormone therapy**, such as Lupron Depot®, to bring your testosterone down to very low levels, but it may not be enough to keep the cancer from starting to grow again. When that happens, you may need to add another medication to the one you are already taking.

PSA ↓ When hormone therapy works, your **prostate-specific antigen (PSA)** level drops and stays low

↑ **PSA** But when your hormone therapy stops working, your PSA levels rise, even if your cancer has not spread. That means you have nmCRPC

WHAT IS nmCRPC?



RISING PSA LEVELS MEAN THAT YOUR CANCER COULD SPREAD

- It is *very important* that your doctor monitors your PSA levels. Your PSA levels may rise even if you are on hormone therapy*
- If your PSA levels rise, that's because your prostate cancer is **castration-resistant (CR)**. That means that the prostate cancer keeps growing even when the amount of testosterone in the body is brought down to very low levels



WHY DOES DELAYING THE SPREAD OF CANCER MATTER?

When prostate cancer spreads to other parts of the body, it can cause symptoms like bone pain and worsen fatigue. It's important to talk to your doctor if you feel new symptoms.

THE BOTTOM LINE

TAKE ACTION to delay the spread of cancer to other parts of your body.

*Hormone therapy includes gonadotropin-releasing hormone (GnRH), such as Lupron Depot® (drug treatment), or surgery that lowers testosterone. Lupron Depot is a registered trademark of AbbVie Inc.

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

WHEN IT'S TIME TO TAKE ACTION, THERE'S NUBEQA



WHAT IS NUBEQA?

NUBEQA is a pill for 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.



Actual pill size.

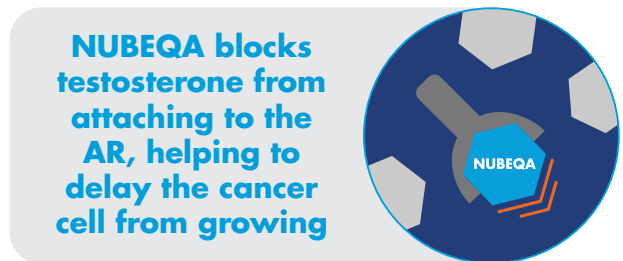
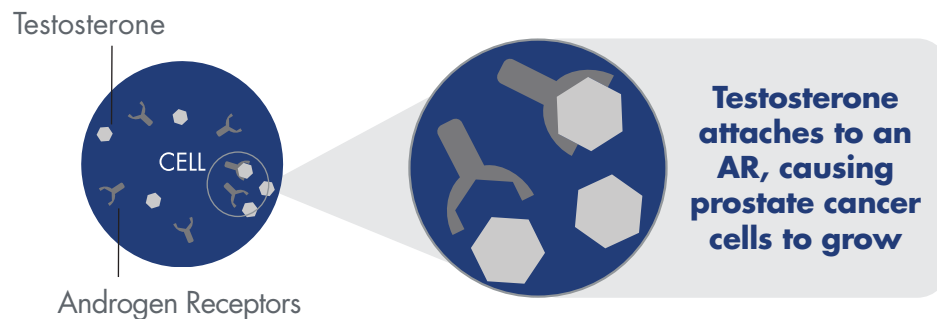


**NUBEQA HELPS YOU LIVE
FOR WHAT YOU LOVE**

See overall survival data on page 8

HOW NUBEQA WORKS

Within every prostate cell, there are special molecules called androgen receptors, or ARs for short. When testosterone attaches to an AR, it causes cancer cells to grow. NUBEQA attaches to the AR and blocks testosterone from attaching to it, which helps delay cancer growth.



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)

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

NUBEQA IS CLINICALLY PROVEN

NUBEQA HAS BEEN PROVEN TO WORK IN THE LARGEST CLINICAL TRIAL OF ITS KIND

NUBEQA was studied in a clinical trial with more than 1500 men with nmCRPC. In this study, 955 men added NUBEQA to their hormone therapy* and 554 received hormone therapy alone. This study measured the length of time living without the cancer spreading to other parts of the body, also called **metastasis-free survival (MFS)**. The study also measured **overall survival (OS)**, which is how long a person may live after starting therapy.

ADDING NUBEQA HELPED KEEP nmCRPC IN ITS PLACE

In a clinical trial

**MEN LIVED
2X
LONGER**

without their prostate cancer spreading to other parts of the body when they added NUBEQA to hormone therapy vs hormone therapy alone (median[†] 3.4 years vs 1.5 years)

*Hormone therapy includes drug treatments or surgery that lowers testosterone.

[†]Median is the middle value in a set of numbers, not the average.

IMPORTANT SAFETY INFORMATION (cont'd)

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

- 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



NUBEQA HELPS YOU LIVE FOR WHAT YOU LOVE

31%
LOWER RISK OF DEATH

NUBEQA MAY ALSO HELP YOU LIVE LONGER

The study also showed that NUBEQA significantly extended OS compared with hormone therapy* alone.

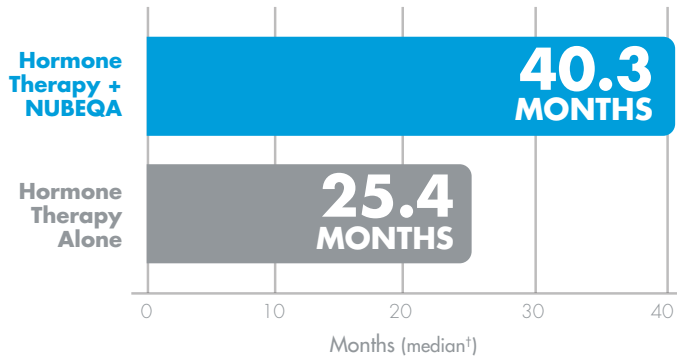
- NUBEQA extended OS by lowering the risk of death by 31% compared with hormone therapy alone

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

ADDING NUBEQA TO HORMONE THERAPY* OFFERS MEN OTHER BENEFITS

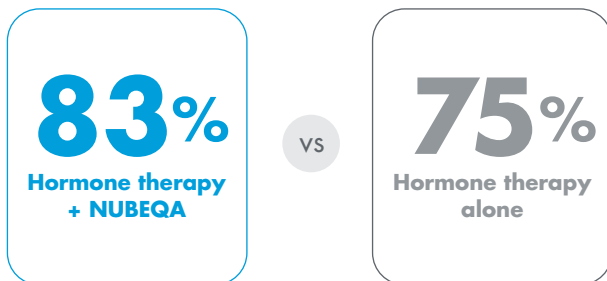
NUBEQA GAVE MEN MORE TIME WITHOUT PAIN

In the same clinical trial, hormone therapy + NUBEQA relieved pain by nearly 15 months longer than hormone therapy alone.



NUBEQA CAN DELAY THE START OF CHEMOTHERAPY

Also in the clinical trial, more men on hormone therapy + NUBEQA had not started chemotherapy at 3 years compared with men who stayed on hormone therapy alone.



*Hormone therapy includes drug treatments or surgery that lowers testosterone.

†Median is the middle value in a set of numbers, not the average.



NUBEQA LOWERED PSA LEVELS

In a clinical trial, NUBEQA lowered PSA levels by an average of more than 90%

PSA LEVELS

90%

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.

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

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.

COMMON SIDE EFFECTS WITH NUBEQA

The most common side effects of hormone therapy + NUBEQA vs hormone therapy* alone are:

- Increase in liver function tests (16% vs 7% on hormone therapy alone)
- Decreased white blood cells (neutropenia; 20% vs 9% on hormone therapy alone)
- Feeling more tired than usual (16% vs 11% on hormone therapy alone)
- Pain in arm, leg, hand, or foot (6% vs 3% on hormone therapy alone)
- Rash (3% vs 1% on hormone therapy alone)

Overall, serious side effects with NUBEQA were moderately higher than those with hormone therapy alone.

- Serious side effects happened in 25% of men who added NUBEQA to hormone therapy compared with 20% who took hormone therapy alone
- Serious side effects that happened in 1% or more of men who added NUBEQA to their hormone therapy included: not being able to urinate completely, pneumonia, and blood in the urine

*Hormone therapy includes drug treatments or surgery that lowers testosterone.

IN A CLINICAL TRIAL

When NUBEQA was added to hormone therapy,
**MOST MEN (84%) DID NOT REPORT
 FEELING MORE TIRED THAN USUAL**

(Men who did feel more tired than usual:
 16% vs 11% on hormone therapy alone)

Sometimes side effects can cause a person to stop treatment when another treatment is added.

IN A CLINICAL STUDY, THE TOLERABILITY PROFILE OF NUBEQA ENABLED MOST PATIENTS TO STAY ON THERAPY

There was no difference in the percentage of men (9%) who permanently stopped treatment due to side effects between those who took hormone therapy* + NUBEQA and those who took hormone therapy alone.

That means that most men (more than 90%) did not permanently stop taking NUBEQA due to side effects, similar to men who took hormone therapy alone.

- Side effects that caused men to permanently stop taking NUBEQA were heart failure (0.4%) and death (0.4%)

13% of men had to stop taking NUBEQA and then start it again because of side effects.

- The most common side effects that caused men to stop taking NUBEQA and then start it again were high blood pressure (hypertension; 0.6%), diarrhea (0.5%), and pneumonia (0.5%)

6% of men taking NUBEQA had to reduce their dosage because of side effects.

- The most common side effects that caused men to reduce their dosage included fatigue (0.7%), high blood pressure (hypertension; 0.3%), and nausea (0.3%)

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.

HOW TO TAKE NUBEQA

TAKE NUBEQA EXACTLY AS YOUR DOCTOR TELLS YOU

**TAKE YOUR
PRESCRIBED
DOSE OF NUBEQA
2 TIMES A DAY
WITH FOOD**



Pills not actual size.

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

- 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**

FOLLOW YOUR DOCTOR'S INSTRUCTIONS WHILE TAKING NUBEQA

- Your doctor may change your dose if needed. Do not stop taking your prescribed dose of NUBEQA without talking with your doctor first
- 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)
- If you take more NUBEQA than prescribed, call your healthcare provider right away

TIP

Set a reminder on your phone or put the NUBEQA magnet on your refrigerator to remind you when to take NUBEQA

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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

*Hormone therapy includes drug treatments or surgery that lowers testosterone.

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


**NUBEQA HELPS YOU LIVE
FOR WHAT YOU LOVE**

See overall survival data on [page 8](#)


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 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 NUBEQAacopyprogram.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.

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

FOR PEOPLE WHO CARE FOR SOMEONE WITH PROSTATE CANCER

WHERE TO FIND MORE INFORMATION



TAKE CARE OF YOURSELF

Caring for a person with cancer can be difficult. You may have many feelings that can affect you in many ways. It's important to make sure you care for yourself as well. Taking care of yourself will help you to give the best support to your loved one.

Here are some ways to deal with the stress of caring for someone with cancer:



Eat healthy and exercise



Do things you enjoy and get out of the house; for example, meet a friend for lunch or take a walk



Ask for help from family and friends in caring for your loved one



Seek out help from a support group or mental health professional

Several of the organizations listed on the next page have resources for caregivers. The booklet "Caregiving for a Loved One With Prostate Cancer" and other resources are available from **CANCERCARE**® at www.cancercare.org/publications.

THE FOLLOWING ORGANIZATIONS OFFER PATIENT AND CAREGIVER SUPPORT

CANCERABCs™
www.cancerabcs.org
 1-516-445-2026

CANCERCARE®
www.cancercare.org
 1-800-813-HOPE
 (1-800-813-4673)

CANCER SUPPORT COMMUNITY
www.cancersupportcommunity.org
 1-888-793-9355

MALECARE
www.malecare.org
 1-212-673-4920

PROSTATE CANCER FOUNDATION
www.pcf.org
 1-800-757-CURE
 (1-800-757-2873)

PROSTATE CANCER INTERNATIONAL
www.pcainternational.org
www.prostatecancerinfolink.net

PROSTATE CANCER RESEARCH INSTITUTE (PCRI)
www.pcri.org
 1-310-743-2116

PROSTATE CONDITIONS EDUCATION COUNCIL (PCEC)
www.prostateconditions.org
 1-866-4PROST8
 (1-866-477-6788)

PROSTATE HEALTH EDUCATION NETWORK (PHEN)
www.prostatehealthd.org
 1-617-481-4020

ZERO—THE END OF PROSTATE CANCER
www.zerocancer.org
 1-202-463-9455

TIP Ask your doctor for a NUBEQA patient starter kit for additional support and reminders

MY TREATMENT TEAM

ONCOLOGIST

Name _____ Phone # _____

E-mail _____

UROLOGIST

Name _____ Phone # _____

E-mail _____

PRIMARY CARE DOCTOR

Name _____ Phone # _____

E-mail _____

NURSE

Name _____ Phone # _____

E-mail _____

CAREGIVER

Name _____ Phone # _____

E-mail _____

SPECIALTY PHARMACY

Name _____ Phone # _____

E-mail _____

TIP

Some men find it helpful to learn as much as possible about their cancer. See [page 19](#) of this brochure for a list of organizations that offer information about cancer

WHAT SHOULD YOU DISCUSS WITH YOUR DOCTOR?

Take a minute to answer the questions below so that you can discuss with your doctor how NUBEQA can fit into your current lifestyle.

How often are you able to exercise with your current hormone therapy?*

How do you like to spend your free time?

Are you able to spend a lot of time with family and friends?

Do any side effects prevent you from enjoying your daily activities?

Do you have a routine meal schedule?

What other medical conditions do you have?

What other medicines do you take?

*Hormone therapy includes drug treatments or surgery that lowers testosterone.



NUBEQA HELPS YOU LIVE FOR WHAT YOU LOVE

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

NUBEQA clinical study was designed to measure metastasis-free survival (MFS) and also overall survival (OS). NUBEQA extended OS by lowering the risk of death by 31% compared with hormone therapy alone.

IMPORTANT SAFETY INFORMATION

The most common side effects of NUBEQA in people with nmCRPC include (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.

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

