

NUBEQA® (darolutamide) 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 women and children.

IMPORTANT SAFETY INFORMATION

NUBEQA can harm unborn babies and cause loss of pregnancy. Men with female partners who may become pregnant should use effective birth control (contraception) during treatment and for 1 week after the last dose of NUBEQA.



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

TAKE ACTION -

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



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

THIS BROCHURE IS FOR YOU.

Lupron Depot is a registered trademark of AbbVie Inc.

IMPORTANT SAFETY INFORMATION (cont'd)

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

• Have kidney or liver problems

GOOD TO KNOW

TAKING ACTION

When you need more than your current hormone therapy*
Rising PSA Levels Mean That Your Cancer Could Spread
CHOOSING NUBEQA
When it's time to take action, there's NUBEQA
How NUBEQA works
NUBEQA has clinical proof
How to take NUBEQA
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Support services for men taking NUBEQA
MORE INFORMATION
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What should you discuss with your doctor?
Glossary
Important facts about NUBEQA



Take notes on <u>page 21</u> at each visit with your doctor so you can refer to them later

Throughout the brochure you'll see **bolded terms**. Flip to <u>page 20</u> of this brochure for a glossary of these terms.



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.

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

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

mm cRPC? CR pC non-metastatic castration-resistant prostate cancer The cancer has NOT Cancer that starts in the prostate gland

and keeps growing even when the

amount of testosterone in the body

is brought down to very low levels

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

spread to other parts

of the body

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 <u>castration-resistant (CR)</u>. That means that the prostate cancer keeps growing even when the amount of testosterone in the body is brought down to very low levels



CANCER IN
THE PROSTATE



CANCER SPREADING
OUTSIDE THE PROSTATE

WHY DOES DELAYING THE SPREAD OF CANCER MATTER?

THE GOAL OF

OF CANCER

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.

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



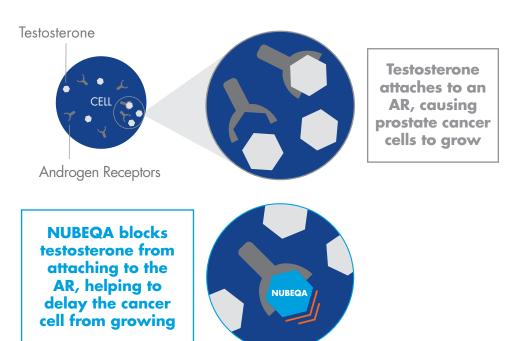
WHAT IS NUBEQA?





HOW NUBEQA WORKS

Within every prostate cell, there are special molecules called androgen receptors, or AR 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 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



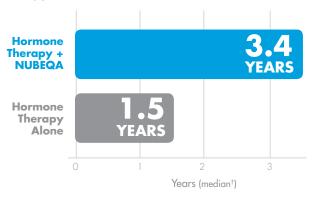
NUBEQA HAS CLINICAL PROOF

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, men received either hormone therapy* + NUBEQA (955 men) or hormone therapy alone (554 men). This study measured the length of time living without the prostate 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.

NUBEQA DELAYED THE SPREAD OF CANCER TO OTHER PARTS OF THE BODY

The study showed that men who received NUBEQA lived more than twice as long without their cancer spreading compared with men who received hormone therapy alone.





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 31%
LOWER RISK
OF DEATH



THE BOTTOM LINE

With NUBEQA added to hormone therapy,*

IT'S POSSIBLE TO LIVE TWICE AS LONG WITHOUT YOUR PROSTATE
CANCER SPREADING TO OTHER PARTS OF YOUR BODY.

NUBEQA MAY ALSO HELP YOU LIVE LONGER.

IMPORTANT SAFETY INFORMATION (cont'd)

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

- For women: tell your healthcare provider if you are:
 - pregnant or plan to become pregnant. NUBEQA can cause harm to your unborn baby and loss of pregnancy (miscarriage)
 - breastfeeding or plan to breastfeed.
 It is not known if NUBEQA passes into breast milk



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

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

HOW TO TAKE NUBEQA

TAKE NUBEQA EXACTLY AS YOUR DOCTOR TELLS YOU

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





vith food Evening 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





HOW TO TAKE NUBEQA (CONT'D)

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



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)

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 without talking to your healthcare provider.



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

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:

- 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)
- Decreased white blood cells (neutropenia; 20% vs 9% on hormone therapy alone)
- Changes in liver function tests (16% vs 7% on hormone therapy alone)

THE BOTTOM LINE

DISCUSS SIDE EFFECTS with your treatment team.

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 to 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



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

In a clinical trial, when NUBEQA was added to hormone therapy,* it did not cause more men to permanently stop treatment due to side effects.

The same percentage of men (9%) permanently stopped taking NUBEQA + hormone therapy as those who took hormone therapy alone. †

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

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

- *Hormone therapy includes drug treatments or surgery that lowers testosterone.
- [†] Side effects that caused men to permanently stop taking NUBEQA were heart failure (0.4%) and death (0.4%).
- [‡] 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%).
- § 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%).



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

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 NUBECA



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 Access Services by Bayer.



800-288-8374

MONDAY-FRIDAY 9:00 am-6:00 pm (ET)

NUBEQA IS HERE FOR YOU



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 NUBEGAcopayprogram.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 pages 22-23 for the Important Facts about NUBEQA.





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 **CANCERCAIPE®** at www.cancercare.org/publications.

WHERE TO FIND MORE INFORMATION

THE FOLLOWING ORGANIZATIONS OFFER PATIENT AND CAREGIVER SUPPORT

CANCERABCs™

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

CANCERCATE®

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.prostatehealthed.org www.rapcancer.org 1-617-481-4020

US TOO INTERNATIONAL PROSTATE CANCER EDUCATION & SUPPORT NETWORK

www.ustoo.org 1-800-80-USTOO (1-800-808-7866)

ZERO—THE END OF PROSTATE CANCER

www.zerocancer.org 1-202-463-9455



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		
NUIDCE		
	Phone #	
E-mail		
CAREGIVER		
	Phone #	
E-mail		
SPECIALTY PHARMACY		
Name	Phone #	
E-mail		

Some men find it helpful to learn as much as possible about their cancer. See page 17 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.

GLOSSARY

Castration-resistant (CR): Prostate cancer that keeps growing even when the amount of testosterone in the body is reduced to very low levels.

Hormone therapy: Includes gonadotrophin-releasing hormone (GnRH), such as Lupron Depot® (drug treatment), or surgery that lowers testosterone.

Metastasis: The spread of cancer to other parts of the body.

Metastasis-free survival (MFS): A term used to define how long a man lives before his prostate cancer spreads to other parts of his body.

Non-metastatic (nm): Cancer that has not spread to other places from its original location in the body.

Overall survival (OS): How long a person may live after starting therapy.

Prostate-specific antigen (PSA): PSA is a protein found in the blood. It is used to track changes in prostate cancer.

Testosterone: Called the "male hormone," it is an androgen-type hormone that causes men's secondary sexual characteristics to develop. In men with prostate cancer, testosterone can also cause the cancer to grow and spread.

IMPORTANT SAFETY INFORMATION (cont'd)

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 tests that determine how your liver works (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 doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

NOTES



advice from a



prostate-cancer patient



advice from a caregiver





IMPORTANT FACTS ABOUT NUBEQA®

(darolutamide) tablets (new-BEH-kah)

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 women and children.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING NUBEQA?

Tell your healthcare provider about all your medical conditions, including if you:

- Have kidney or liver problems
- 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
- For women: tell your healthcare provider if you:
- are pregnant or plan to become pregnant. NUBEQA can cause harm to your unborn baby and loss of pregnancy (miscarriage)
- 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.

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).

HOW SHOULD I TAKE NUBEQA? (cont'd)

- If you miss a dose of NUBEQA, take your normal dose as soon as possible before your next scheduled dose. Do not take 2 doses together to make up for a missed dose.
- If you take more NUBEQA than prescribed, call your healthcare provider right away.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF NUBEQA?

- Feeling more tired than usual
- Arm, leg, hand, or foot pain
- Rash
- Decreased white blood cells (neutropenia)
- Changes in tests that determine how your liver works (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.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of NUBEQA. Call your doctor for medical advice about side effects.

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.

The information provided here is not comprehensive.

TO LEARN MORE ABOUT NUBEQA:

- Talk to your healthcare provider or pharmacist
- Visit www.nubega.com to obtain the FDA-approved product labeling
- Call 1-888-842-2937

You may report side effects or quality complaints of products to the FDA by visiting www.fda.gov/medwatch, or call 1-800-FDA-1088.





Please see additional Important Safety Information throughout and pages 22-23 for the Important Facts about NUBEQA.



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