For nmCRPC

Non-Metastatic Castration-Resistant Prostate Cancer



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)

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

• 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' | • | | <u>4</u> |
|---|---|------|--------------|
| Rising PSA levels mean that your cancer could spread | | | <u>5</u> |

CHOOSING NUBEQA

| When it's time to take action, there's NUBEQA |
|---|
| How NUBEQA works |
| NUBEQA is clinically proven |
| NUBEQA offers men other benefits |
| Possible side effects with NUBEQA |
| How to take NUBEQA |
| Support services for men taking NUBEQA |

MORE INFORMATION

| For people who care for someone with prostate cancer <u>18</u> |
|--|
| Where to find more information <u>19</u> |
| My treatment team |
| What should you discuss with your doctor? |
| Glossary |



Take notes on <u>page 23</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 22</u> of this brochure for a glossary of these terms.

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

WHEN YOU NEED MORE THAN YOUR **CURRENT HORMONE THERAPY***

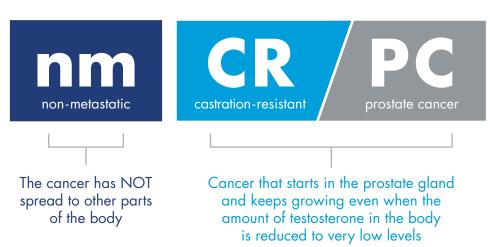
When you have prostate cancer, the **testosterone** in your body causes it to grow and spread. You may already be on a **hormone therapy**, such as Lupron Depot[®], to bring your testosterone down to very low levels, but it may not be enough to keep the cancer from starting to grow again. When that happens,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

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

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





CANCER SPREADING OUTSIDE THE PROSTATE

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.

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

HOW NUBEQA WORKS



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.



See overall survival data on page 8

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.



NUBEQA blocks testosterone from attaching to the AR, helping to delay the cancer cell from growing



IMPORTANT SAFETY INFORMATION (continued)

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

- 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)

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

ln a clinical trial 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.

MEN LIVED

IMPORTANT SAFETY INFORMATION (continued)

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

- 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



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.

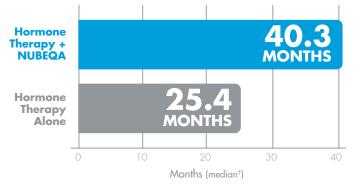
• NUBEQA extended OS by lowering the risk of death by 31% compared with hormone therapy alone

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

ADDING NUBEQA TO HORMONE THERAPY* OFFERS MEN OTHER BENEFITS

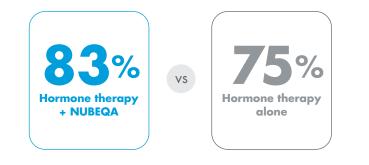
NUBEQA GAVE MEN MORE TIME WITHOUT PAIN

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.





IMPORTANT SAFETY INFORMATION (continued)

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 <u>Prescribing Information</u>.

*Hormone therapy includes drug treatments or surgery that lowers testosterone. [†]Median is the middle value in a set of numbers, not the average.

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 (AST increased; 23% vs 14% 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)
- Increase in liver function tests (bilirubin increased; 16% vs 7% on hormone therapy alone)
- Pain in arm, leg, hand, or foot (6% vs 3% on hormone therapy alone)
- Rash (4% vs 1.4% 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



Evening with food

0

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



NUBEQA HELPS YOU LIVE FOR WHAT YOU LOVE

See overall survival data on page 8

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 (continued)

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:

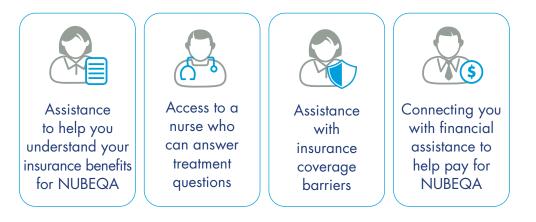
• **Heart disease.** Blockage of the arteries in the heart (ischemic heart disease) that can lead to death has happened in some people during treatment with NUBEQA. Your healthcare provider will monitor you for signs and symptoms of heart problems during your treatment with NUBEQA. Call your healthcare 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.

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:



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

Access Services

by Baver[™]





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).[‡]

Check to see if you are eligible for the Nubeqa Copay Program by clicking here.

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.[§]

¹ 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.

¹Restrictions 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.

FOR PEOPLE WHO CARE FOR SOMEONE WITH PROSTATE CANCER

WHERE TO FIND **MORE INFORMATION**



TAKE CARE OF YOURSELF

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

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



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

THE FOLLOWING ORGANIZATIONS OFFER PATIENT AND CAREGIVER SUPPORT

CANCERABCs[™]

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

CANCER*COP*®

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 1-617-481-4020

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

WHAT SHOULD YOU DISCUSS WITH YOUR DOCTOR?

| ONCOLOGIST | | Take a minute to answer the questions below so that you can discuss | | | | |
|--------------------|---------|--|--|--|--|--|
| Name | Phone # | with your doctor how NUBEQA can fit into your current lifestyle. | | | | |
| E-mail | | How often are you able to exercise with your current hormone therapy?* | | | | |
| UROLOGIST | | | | | | |
| Name | Phone # | How do you like to spend your free time? | | | | |
| E-mail | | | | | | |
| PRIMARY CARE DOCTO | OR | | | | | |
| Name | Phone # | Are you able to spend a lot of time with family and friends? | | | | |
| E-mail | | | | | | |
| NURSE | | Do any side effects prevent you from enjoying your daily activities? | | | | |
| Name | Phone # | | | | | |
| E-mail | | | | | | |
| CAREGIVER | | Do you have a routine meal schedule? | | | | |
| Name | Phone # | | | | | |
| E-mail | | What other medical conditions do you have? | | | | |
| SPECIALTY PHARMACY | r | | | | | |
| Name | Phone # | What other medicines do you take? | | | | |
| E-mail | | | | | | |

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

NOTES



IMPORTANT SAFETY INFORMATION (continued)

NUBEQA may cause serious side effects, including (continued):

• **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

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

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



GLOSSARY

Please see additional Important Safety Information throughout and the full Prescribing Information.

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 gonadotropin-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.

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.

Pronounced new-BEH-kah

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 (non-metastatic castration-resistant prostate cancer or nmCRPC),or
- That has spread to other parts of the body and responds to medical or surgical treatment that lowers testosterone (metastatic hormone-sensitive prostate cancer or mHSPC), in combination with docetaxel
- It is not known if NUBEQA is safe and effective in females or children.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER 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 partner who may become pregnant. Males who have female partners who may become pregnant should use effective birth
- 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)
- 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) 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 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?

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.

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

Rash

- Increase in liver function tests
- Arm, leg, hand or foot pain
- Decreased white blood cells (neutropenia)
- Feeling more tired than usual

The most common side effects of NUBEQA when used in combination with docetaxel in people with mHSPC 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 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 NUBEQA.com to obtain the FDA-approved product labeling
- Call 1-888-842-2937

NUBEQA HELPS YOU LIVE FOR WHAT YOU LOVE

Learn more at 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 (continued)

The most common side effects of NUBEQA in people with nmCRPC include (continued):

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 <u>Prescribing Information</u>.



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