

# LIFE CHANGES WHAT YOU LOVE DOESN'T HAVE TO

# A guide to NUBEQA®

**NUBEQA** is pronounced new-BECCA

#### 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 a medical or surgical treatment that lowers testosterone
- that has spread to other parts of the body and responds to a medical or surgical treatment that lowers testosterone
- that has spread to other parts of the body and responds to a medical or surgical treatment that lowers testosterone in combination with docetaxel.

It is not known if NUBEQA is safe and effective in females 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
- have kidney or liver problems

# **ABOUT NUBEQA®**

NUBEQA is a prescription medicine that's approved to treat certain types of advanced prostate cancer

> Interested in information about NUBEQA results or caregiver-specific resources? Use the buttons below to directly navigate.

If your prostate cancer **has spread** to other parts of the body (metastatic) and **responds to ADT,**\* learn about the NUBEQA clinical studies relevant to you.

See results from these clinical studies

If your prostate cancer **has not spread** to other parts of the body (non-metastatic) and **does not respond to ADT,** learn about the NUBEQA clinical study relevant to you.

See results from this clinical study

# If you're a caregiver, head to page 13 for support.

\*ADT refers to a medical or surgical treatment that lowers testosterone.

#### **IMPORTANT SAFETY INFORMATION (continued)**

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

- 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



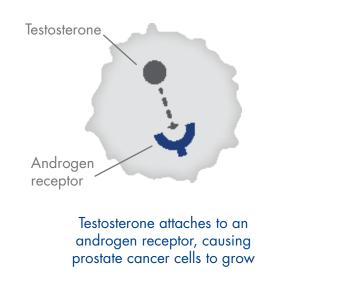
# **HOW NUBEQA® WORKS**

## What makes prostate cancer cells grow?

Prostate cancer cells contain special proteins called androgen receptors. When the hormone testosterone attaches to these receptors, it can trigger processes that cause prostate cancer cells to grow.

## How does NUBEQA delay prostate cancer growth?

NUBEQA is an androgen receptor blocker, which means **it attaches to the androgen receptors inside cancer cells and blocks testosterone from attaching**. By being designed to stop testosterone attaching, NUBEQA may help delay cancer cells from growing.





**NUBEQA** blocks testosterone from attaching to the androgen receptor to help delay the cancer cell from growing

#### **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.

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.



# TAKING NUBEQA®

# NUBEQA is a pill

# 2 tablets, 2X a day with food

Follow your doctor's instructions while taking NUBEQA



# How should I take NUBEQA?

- Take NUBEQA exactly as your doctor tells you
- 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
- Swallow two tablets whole, 2 times a day, with food
- Unless otherwise advised by your doctor, continue on ADT\* while taking NUBEQA
- If you take more NUBEQA than prescribed, call your doctor right away

## What should I do if I miss a dose of NUBEQA?

- Take your prescribed dose as soon as you remember
- Do not take 2 doses together to make up for a missed dose

\*ADT refers to a medical or surgical treatment that lowers testosterone.

#### **IMPORTANT SAFETY INFORMATION (continued)**

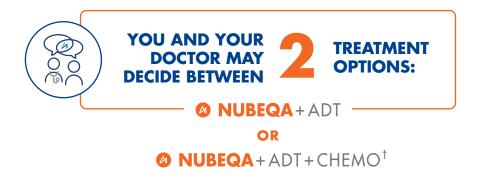
#### NUBEQA may cause serious side effects, including:

• **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.



# NUBEQA® OFFERS OPTIONS FOR A PERSONALIZED TREATMENT DECISION

If you have **metastatic** prostate cancer that responds to ADT\*



Dosing with chemotherapy for metastatic prostate cancer that responds to ADT

**NUBEQA is not chemotherapy,** but one of its approved uses is in combination with a type of chemotherapy called docetaxel for the treatment of metastatic prostate cancer that responds to ADT.

- Chemotherapy is given as an intravenous (IV) infusion in your arm once every 3 weeks for up to 6 cycles
- All 6 cycles of chemotherapy will be given within the first ~5 months of treatment with NUBEQA
- Your doctor may change, delay, or stop treatment with chemotherapy if needed
- Once chemotherapy is complete, treatment with NUBEQA can be continued as prescribed by your doctor

\*ADT refers to a medical or surgical treatment that lowers testosterone. \*Chemotherapy=docetaxel.

#### **IMPORTANT SAFETY INFORMATION (continued)**

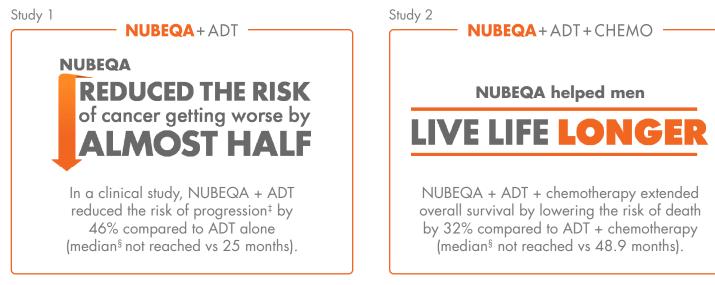
NUBEQA may cause serious side effects, including (continued):

• **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 during treatment with NUBEQA.



## **PROVEN RESULTS WITH NUBEQA®** FOR MEN WITH **METASTATIC PROSTATE CANCER THAT RESPONDS TO ADT\***

NUBEQA was evaluated in two different clinical trials, with and without chemotherapy.<sup>†</sup> This gives you and your doctor options to tailor your treatment plan to your needs.



At the time of analysis, 29% (128 out of 446) of men taking NUBEQA + ADT had cancer worsening via scans or were no longer living compared to 42% (94 out of 223) of men taking ADT alone. At the time of analysis, 35% (229 out of 651) of men taking NUBEQA + ADT + chemotherapy were no longer living compared to 46% (304 out of 654) of men taking ADT + chemotherapy.

\*ADT refers to a medical or surgical treatment that lowers testosterone. \*Chemotherapy=docetaxel.

<sup>†</sup>rPFS is measured by the cancer worsening via scans or the participant no longer living.

<sup>§</sup>Median is the middle value in a set of numbers, not the average.

#### **IMPORTANT SAFETY INFORMATION (continued)**

The most common side effects of NUBEQA include:

- increase in liver function tests
- decreased white blood cells (neutropenia)
- feeling more tired than usual

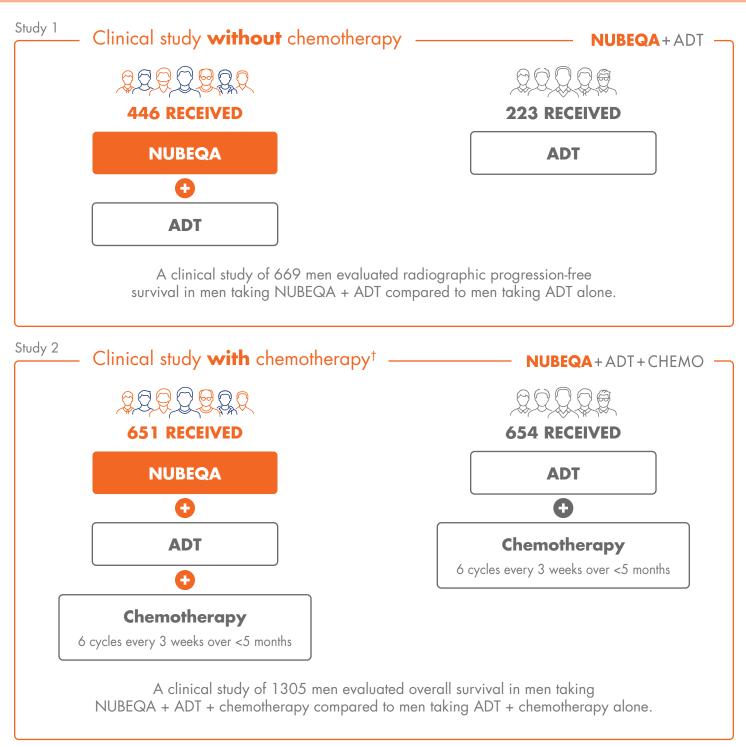
#### The most common side effects of NUBEQA in combination with docetaxel include:

- 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



### HOW NUBEQA® WAS STUDIED IN MEN WITH METASTATIC PROSTATE CANCER THAT RESPONDS TO ADT\*



\*ADT refers to a medical or surgical treatment that lowers testosterone. <sup>†</sup>Chemotherapy=docetaxel.

#### **IMPORTANT SAFETY INFORMATION (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.

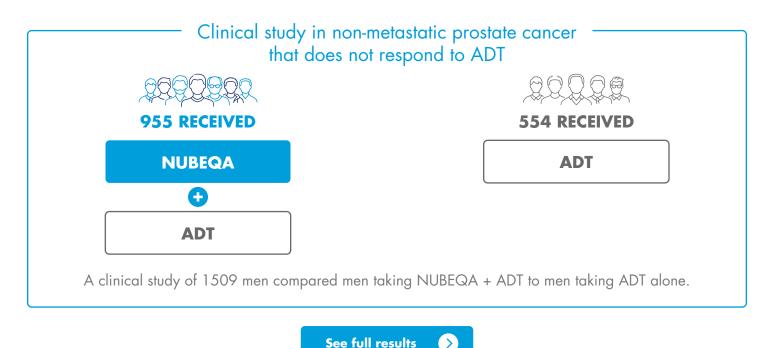




# NUBEQA HELPED MEN LIVE 2X LONGER WITHOUT CANCER SPREADING vs ADT glone

Men who were treated with NUBEQA + ADT lived more than twice as long without their cancer spreading to other parts of the body, compared with men who took ADT alone (median<sup>†</sup> 3.4 years vs 1.5 years).

At the time of analysis, 23% (221 out of 955) of men taking NUBEQA + ADT had cancer spreading or were no longer living compared to 39% (216 out of 554) of men taking ADT alone.





#### **IMPORTANT SAFETY INFORMATION (continued)**

These are not all the possible side effects of NUBEQA.

Call your healthcare provider for medical advice about side effects. You are encouraged to report side effects or quality complaints of products to the FDA by visiting **<u>www.fda.gov/medwatch</u>** or calling **<u>1-800-FDA-1088</u>**.



# 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 during treatment with NUBEQA.

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



Increase in liver function tests



Decreased white blood cells (neutropenia)



Feeling more tired than usual

#### The most common side effects of NUBEQA in combination with docetaxel 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 their 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**.

\*ADT refers to a medical or surgical treatment that lowers testosterone.

#### **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)





## SIDE EFFECTS IN MEN WITH NON-METASTATIC PROSTATE CANCER THAT DOES NOT RESPOND TO ADT\*

# 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 during treatment with NUBEQA.

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



function tests



Decreased white blood cells (neutropenia)



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.

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**.

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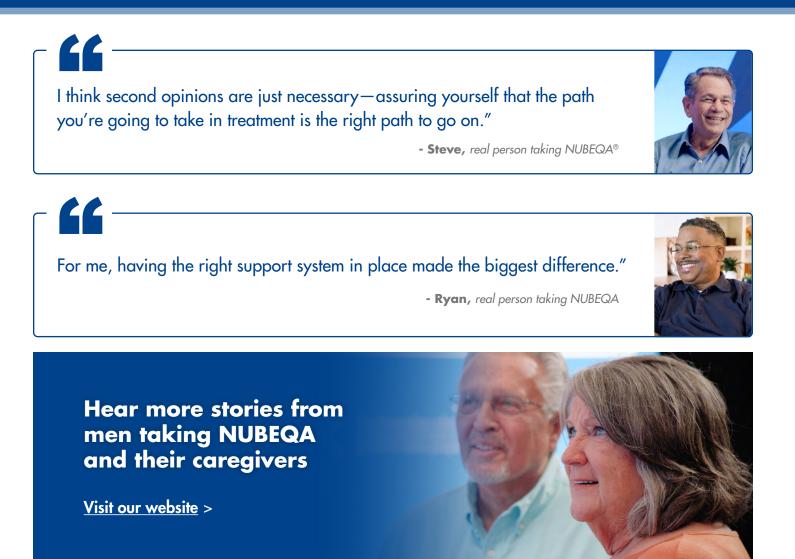
#### **IMPORTANT SAFETY INFORMATION (continued)**

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

- 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)
- 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



# **STORIES FROM REAL PEOPLE**



# Have a story of your own to share?

Sign up to share your NUBEQA story, or call **1-800-288-8374** to share your story with a live Bayer representative.



#### **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.



## Support for you while taking NUBEQA®

Access Services by Bayer<sup>™</sup> can help you with information about paying for NUBEQA. To speak with a specialist, call **1-800-288-8374**, available Monday - Friday, 8 AM - 8 PM (ET).

# IF YOU ARE NEW TO NUBEQA

Ask your provider about the 1-month Free Trial Program.



#### IF YOU HAVE COMMERCIAL INSURANCE

You may be eligible for the NUBEQA <u>\$0 Co-Pay Program</u>. NUBEQA: <sup>\$</sup>O PROGRAM PROGRAM Construction of the NUBEQA (arolutamide) But (arolutamide) But

#### IF YOU HAVE MEDICARE OR MEDICAID

You may qualify for help paying out-of-pocket costs for NUBEQA.

Government-funded assistance may be available. Check your eligibility at medicare.gov/your-medicare-costs.

#### Independent foundations may also be able to help.

Cancer*Care*® 1-800-813-4673 HealthWell Foundation<sup>®</sup> 1-800-675-8416 PAN Foundation
1-866-316-7263

The Assistance Fund 1-855-845-3663 Patient Advocate Foundation Co-Pay Relief 1-866-512-3861

## IF YOU DO NOT HAVE INSURANCE

Contact the Bayer US **Patient Assistance Foundation**, a charitable organization that helps eligible patients get Bayer prescription medicine at no cost.

Call **1-866-228-7723** Monday - Friday 9:00 AM - 6:00 PM (ET) or visit the foundation website at **patientassistance.bayer.us** to see if you qualify.

Depending on insurance plans and other factors, the cost of NUBEQA may differ from person to person. To learn about your insurance coverage and paying for NUBEQA, call **1-800-288-8374** to speak with a specialist at Access Services by Bayer.

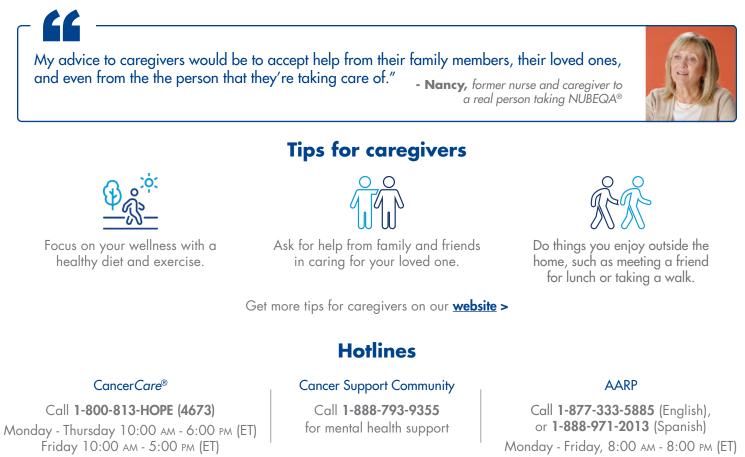
#### **IMPORTANT SAFETY INFORMATION (continued)**

You should not start or stop any medicine before you talk with the healthcare provider that prescribed NUBEQA.



## **Resources made specifically for caregivers**

As a caregiver, it's important to take care of yourself as well as others. The following resources offer tips and support designed specifically for you.



# Prostate cancer support groups

These organizations can help you find local support groups, online peer support, and tips for caregivers of men with prostate cancer.

#### ZERO Prostate Cancer

Prostate Cancer Foundation

#### Prostate Cancer Research Institute

#### FOR MEN TAKING NUBEQA: THANK YOUR CAREGIVER

Select and personalize a thank-you card for those who support you by downloading an option from our website >

#### **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.



Pronounced new-BECCA

#### 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
- that has spread to other parts of the body and responds to a medical or surgical treatment that lowers testosterone
- that has spread to other parts of the body and responds to a medical or surgical treatment that lowers testosterone 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
- have high blood pressure
- have diabetes
- have high amounts of fat or cholesterol in your blood (dyslipidemia)
- 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).
- 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.

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#### 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) 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.
- If you take more NUBEQA than prescribed, call your healthcare provider right away.

Important Facts about NUBEQA are continued on the next page.

Please see full Prescribing Information at NUBEQA.com/Pl.



Pronounced new-BECCA

#### 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 during treatment with NUBEQA.

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

- increase in liver function tests
- decreased white blood cells (neutropenia)
- feeling more tired than usual

#### The most common side effects of NUBEQA in combination with docetaxel include:

- constipation
- rash
- decreased appetite
- bleeding
- weight gain
- high blood pressure

high blood sugar levels

decreased red blood cells (anemia)

- 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 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.

#### 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 Bayer at 1-888-842-2937



Please see full Prescribing Information at NUBEQA.com/Pl.

# To learn more about NUBEQA®, talk to your doctor or visit NUBEQA.com





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