

LIFE CHANGES

WHAT YOU LOVE DOESN'T HAVE TO


NUBEQA[®]
(darolutamide) 300 mg
tablets



A patient guide to NUBEQA[®]

NUBEQA is pronounced new-BECCA

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

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on [page 17-19](#), and the full [Prescribing Information](#).

ABOUT NUBEQA


METASTATIC RESULTS

NON-METASTATIC RESULTS

TAKING NUBEQA

SUPPORT

IMPORTANT FACTS



You and your loved ones have our support

A note from us at Bayer

*If you're feeling overwhelmed after receiving a diagnosis, you are not alone. Whether you have many questions or don't know where to start, **we are here for you.** This guide was created to help you and your loved ones understand your treatment with NUBEQA® and the support available at every step of the way.*

Additional information for caregivers is on page 16.

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on [page 17-19](#), and the full [Prescribing Information](#).


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NUBEQA® offers options for you and your doctor to make a personalized treatment decision



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.



You and your doctor will decide whether NUBEQA fits your treatment needs.

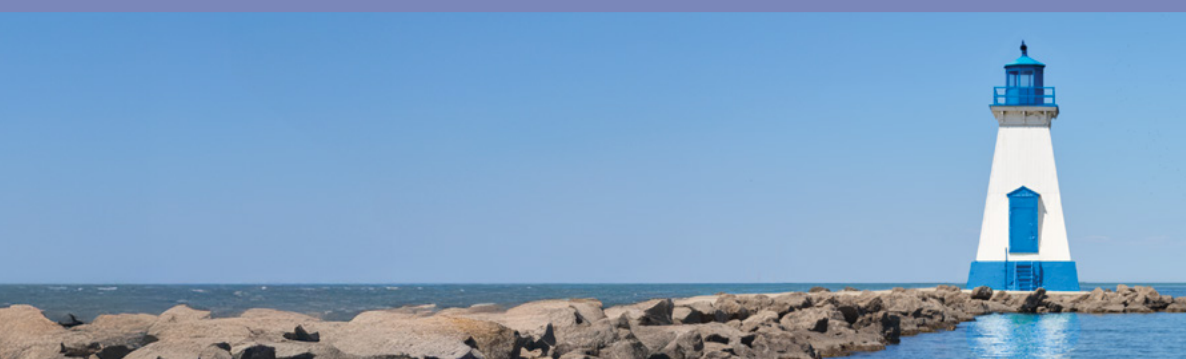
IMPORTANT SAFETY INFORMATION (continued)

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)

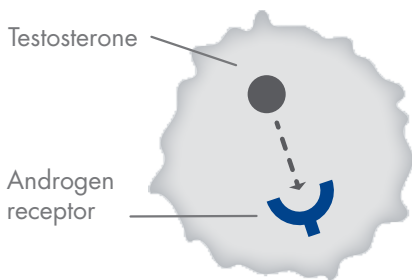
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What makes prostate cancer cells grow?

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.



Testosterone attaches to an androgen receptor, causing prostate cancer cells to grow

IMPORTANT SAFETY INFORMATION (continued)

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

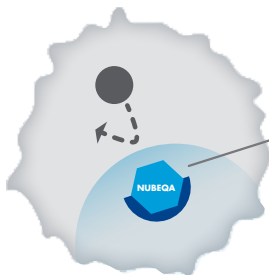
- have a partner who may become pregnant. Males who have female partners who may become pregnant should use effective birth control (contraception) during treatment and for 1 week after the last dose of NUBEQA. Talk with your healthcare provider about birth control methods
- are breastfeeding or plan to breastfeed. It is not known if NUBEQA passes into breast milk

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on [page 17-19](#), and the full [Prescribing Information](#).



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.

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on [page 17-19](#), and the full [Prescribing Information](#).

PROVEN RESULTS WITH NUBEQA®

IN MEN WITH METASTATIC PROSTATE CANCER THAT RESPONDS TO ADT*

In two different clinical studies, NUBEQA delivered proven results.

Study 1

NUBEQA + ADT

NUBEQA

REDUCED THE RISK
of cancer getting worse by
ALMOST HALF

In a clinical study, NUBEQA + ADT reduced the risk of progression[†] by 46% compared to ADT alone (median[‡] not reached vs 25 months).

Radiographic progression-free survival was evaluated in 446 men taking NUBEQA + ADT, compared to 223 men taking ADT alone.

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.

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

[†]rPFS is measured by the cancer worsening via scans or the participant no longer living.

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

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.

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Study 2

NUBEQA + ADT + CHEMO

NUBEQA helped men

LIVE LIFE LONGER

NUBEQA + ADT + chemotherapy[†] extended overall survival by lowering the risk of death by 32% compared to ADT + chemotherapy (median[‡] not reached vs 48.9 months).

Overall survival was evaluated in 651 men taking NUBEQA + ADT + chemotherapy, compared to 654 men taking ADT + chemotherapy.

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.

See more about the study design



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

[†]Docetaxel is an intravenous (IV) chemotherapy infusion that may be used in combination with NUBEQA. Docetaxel was given at a dose of 75 mg/m² every 21 days for 6 cycles. Note 21 days is one cycle.

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

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.

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on [page 17-19](#), and the full [Prescribing Information](#).


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SIDE EFFECTS

IN MEN WITH METASTATIC PROSTATE CANCER THAT RESPONDS TO ADT*

ABOUT NUBEQA

METASTATIC RESULTS

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TAKING NUBEQA

SUPPORT

IMPORTANT FACTS

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

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

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

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on [page 17-19](#), and the full [Prescribing Information](#).


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SIDE EFFECTS (cont'd)

IN MEN WITH METASTATIC PROSTATE CANCER THAT RESPONDS TO ADT*

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.

[†]Docetaxel=chemotherapy.

IMPORTANT SAFETY INFORMATION (continued)

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

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on [page 17-19](#), and the full [Prescribing Information](#).


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In a clinical study,

NUBEQA HELPED

MEN LIVE 2X LONGER

without cancer spreading vs ADT alone

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† 3.4 years vs 1.5 years).

Metastasis-free survival‡ was evaluated in 955 men taking NUBEQA + ADT, compared to 554 men taking ADT alone.

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.

See full results



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

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

‡Metastasis-free survival refers to the length of time living without the prostate cancer spreading to other parts of the body.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of NUBEQA in combination with docetaxel include (continued):

- decreased white blood cells
- low blood calcium levels
- increase in liver function tests

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on page 17-19, and the full [Prescribing Information](#).


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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

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. 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 www.fda.gov/medwatch or calling **1-800-FDA-1088**.

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on page 17-19, and the full [Prescribing Information](#).

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
- If you 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)

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

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

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on page 17-19, and the full [Prescribing Information](#).

You and your doctor can decide if taking NUBEQA with or without chemotherapy* is right for you

NUBEQA is not chemotherapy, but one of its approved uses is in combination with docetaxel (chemotherapy) for the treatment of **prostate cancer that has spread (metastatic) and responds to ADT**.

Dosing schedule with chemotherapy

- 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

*Chemotherapy=docetaxel.

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)
- 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

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on [page 17-19](#), and the full [Prescribing Information](#).


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STORIES FROM REAL PEOPLE



I think second opinions are just necessary—assuring yourself that the path you're going to take in treatment is the right path to go on.” - **Steve**, real person taking NUBEQA®

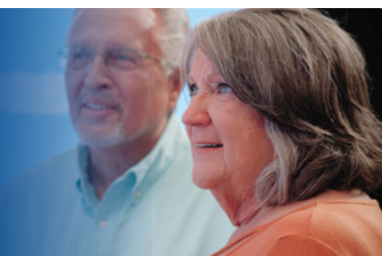


For me, having the right support system in place made the biggest difference.”

- **Ryan**, real person taking NUBEQA



Scan QR code to hear more stories from men taking NUBEQA and their caregivers



Have a story of your own to share?

Sign up at [NUBEQA.com/keep-in-touch](https://www.nubeqa.com/keep-in-touch) or call 1-800-288-8374 to share your story with a live Bayer representative.

IMPORTANT SAFETY INFORMATION (continued)

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

- are breastfeeding or plan to breastfeed. It is not known if NUBEQA passes into breast milk

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on page 17-19, and the full [Prescribing Information](#).


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FINANCIAL ASSISTANCE

Financial assistance options during NUBEQA® treatment

Access Services by Bayer™ can help you with information about paying for NUBEQA. Visit go.bayer.com/patient-assistance for more cost savings information. To speak with a specialist, call **1-800-288-8374**.

IF YOU ARE NEW TO NUBEQA

Ask your provider about the
1-month Free Trial Program



IF YOU HAVE COMMERCIAL INSURANCE

If you have commercial insurance, you may be eligible for the NUBEQA **\$0 Co-Pay Program**



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/basics/costs](https://www.medicare.gov/basics/costs)

Independent foundations may also be able to help

CancerCare®
1-800-813-4673

HealthWell Foundation®
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.

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.

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CAREGIVER SUPPORT & RESOURCES

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.

“ My advice to caregivers would be to accept help from their family members, their loved ones, and even from the person that they're taking care of.”

- **Nancy**, a real former nurse and caregiver to a person taking NUBEQA®



CAREGIVERS NEED CARE TOO



Focus on your wellness with a healthy diet and exercise.



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



Do things you enjoy outside the home, such as meeting a friend for lunch or taking a walk.

HOTLINES

CancerCare®
Call 1-800-813-HOPE (4673)

Cancer Support Community
Call 1-888-793-9355
for mental health support

AARP
Call 1-877-333-5885 (English),
or 1-888-971-2013 (Spanish)

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

IMPORTANT SAFETY INFORMATION (continued)

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

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WHAT IS NUBEQA?

NUBEQA is a prescription medicine used to treat adults with prostate cancer:

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- 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.

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.

Please see full [Prescribing Information](#).

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING NUBEQA? (continued)

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) 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.

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.

Please see full [Prescribing Information](#).

IMPORTANT FACTS ABOUT NUBEQA® (darolutamide) tablets (cont'd)

Pronounced new-BECCA

ABOUT 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 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](https://www.nubeqa.com) to obtain the FDA-approved product labeling
- Call Bayer at 1-888-842-2937

Please see full [Prescribing Information](#).


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or visit NUBEQA.com



ABOUT NUBEQA

METASTATIC RESULTS

NON-METASTATIC RESULTS

TAKING NUBEQA

SUPPORT

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