

NUBEQA® HELPS YOU LIVE FOR WHAT YOU LOVE

NUBEQA is pronounced new-BECCA

NUBEQA EXTENDED OVERALL SURVIVAL BY LOWERING THE RISK OF DEATH

in **nmCRPC** by **31%**
when NUBEQA was added to hormone therapy* vs hormone therapy alone†

[See results in nmCRPC ▶](#)

in **mHSPC** by **32%**
when NUBEQA was added to hormone therapy* + docetaxel (chemotherapy) vs hormone therapy + chemotherapy alone

[See results in mHSPC ▶](#)

Men with **nmCRPC** who took NUBEQA + hormone therapy* lived more than twice as long without prostate cancer spreading to other parts of their body compared with men on hormone therapy alone (median‡ 3.4 years vs 1.5 years).

*Hormone therapy includes drug treatments or surgery that lowers testosterone.
†The clinical study in nmCRPC was designed to measure metastasis-free survival (MFS) and also overall survival.
‡Median is the middle value in a set of numbers.

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**), 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 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)
- 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 pages [18-19](#), and the full [Prescribing Information](#).


NUBEQA®
(darolutamide) 300 mg tablets

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Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).


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UNDERSTANDING PROSTATE CANCER

Knowing your diagnosis can help you discuss treatment options

Prostate cancer takes place in the prostate, a small gland located below the bladder. It happens when the body cannot control the growth of abnormal prostate cells. Prostate cancer may become metastatic, which means it has spread to other parts of the body, such as the bones, lungs, liver, or lymph nodes.

Your doctor will tell you which type of prostate cancer you have. NUBEQA®* is approved to treat two types of prostate cancer:

m → **Metastatic:** has spread to other parts of the body

HS → **Hormone-sensitive:** responds to drug treatments or surgery that lowers testosterone

PC → **Prostate cancer**

mHSPC*
(Metastatic Hormone-Sensitive Prostate Cancer)

- prostate cancer that **has spread** to other parts of the body and that **responds** to drug treatment or surgery that lowers testosterone (hormone therapy)

In this brochure, information about mHSPC is colored **orange**. To learn more about NUBEQA in mHSPC, click below.

*NUBEQA is approved in combination with docetaxel (chemotherapy) for mHSPC.

[See results in mHSPC ▶](#)

nm → **Non-metastatic:** has not spread to other parts of the body

CR → **Castration-resistant:** no longer responds to drug treatments or surgery that lowers testosterone; prostate-specific antigen (PSA) levels may rise

PC → **Prostate cancer**

nmCRPC
(Non-metastatic Castration-Resistant Prostate Cancer)

- prostate cancer that **has not spread** to other parts of the body and that **no longer responds** to drug treatment or surgery that lowers testosterone (hormone therapy)

In this brochure, information about nmCRPC is colored **light blue**. To learn more about NUBEQA in nmCRPC, click below.

[See results in nmCRPC ▶](#)

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)

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).


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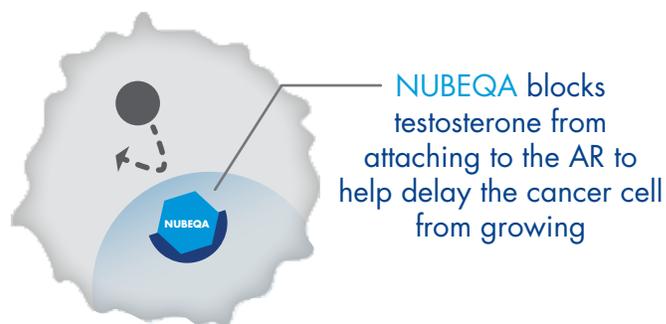
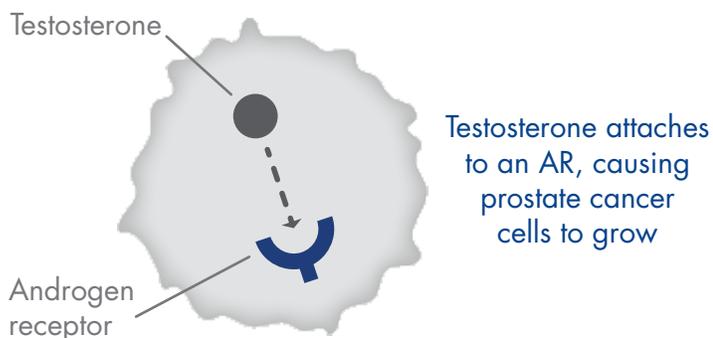
ABOUT NUBEQA®

What Is NUBEQA?

NUBEQA is a type of oral medicine called an **androgen receptor inhibitor**, or an **ARI**. It is not chemotherapy.

How NUBEQA Works

Prostate cancer cells contain molecules called **androgen receptors (ARs)**. When testosterone attaches to an AR, it causes cancer cells to grow. NUBEQA attaches to the AR and blocks testosterone from attaching to help delay cancer cells from growing.



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

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.

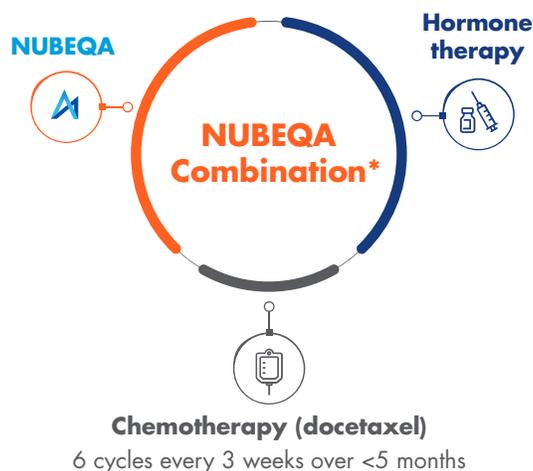
Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).


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ABOUT NUBEQA®

If you have **metastatic hormone-sensitive prostate cancer**, your doctor may consider using a combination of treatments to treat your prostate cancer. The NUBEQA combination* is an option they can consider.



If you have **non-metastatic castration-resistant prostate cancer**, a combination of treatments is one option your doctor can consider using. Your doctor may consider NUBEQA + hormone therapy† to treat your prostate cancer.



Talk to your doctor to learn more about what treatment option may be right for you.

*NUBEQA combination=NUBEQA + hormone therapy with docetaxel (chemotherapy).

†Hormone therapy includes drug treatments or surgery 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.

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).

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PROVEN RESULTS WITH NUBEQA® IN mHSPC

Proven results in metastatic hormone-sensitive prostate cancer (mHSPC)

In a clinical study, men treated with the NUBEQA combination* lived longer

32% lower risk of death
with **NUBEQA** ↓

The NUBEQA combination* extended overall survival by lowering the risk of death by 32% (compared with men who only received hormone therapy† + chemotherapy).

Another way to look at results:

In the study for mHSPC, more men treated with the NUBEQA combination* were alive at 4 years

- 63% of men were still alive with the NUBEQA combination*
- 50% of men were still alive with hormone therapy† + chemotherapy alone

SEE SIDE EFFECTS IN mHSPC ▶

*NUBEQA combination=NUBEQA + hormone therapy with docetaxel (chemotherapy).

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

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

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).

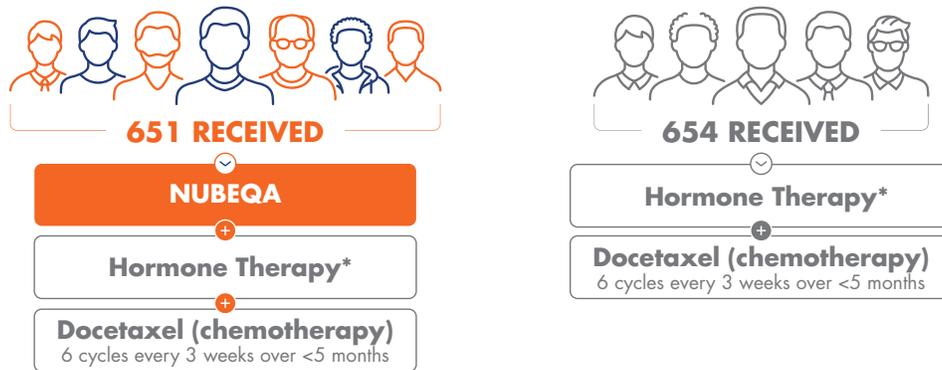



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PROVEN RESULTS WITH NUBEQA® IN mHSPC

Proven results in metastatic hormone-sensitive prostate cancer (mHSPC)

How NUBEQA was studied in mHSPC



A clinical study of 1305 men with mHSPC compared the NUBEQA combination[†] with hormone therapy* + docetaxel (chemotherapy).

In the same study, the NUBEQA combination[†] delayed pain getting worse

21% lower risk of pain worsening
with **NUBEQA**

It took significantly longer for pain to get worse in men with mHSPC who were treated with the NUBEQA combination[†] compared with men who only received hormone therapy* + chemotherapy.

Overall, the NUBEQA combination[†] reduced the risk of pain getting worse by 21%.

SEE SIDE EFFECTS IN mHSPC ▶

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

[†]NUBEQA combination=NUBEQA + hormone therapy with docetaxel (chemotherapy).

IMPORTANT SAFETY INFORMATION (continued)

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

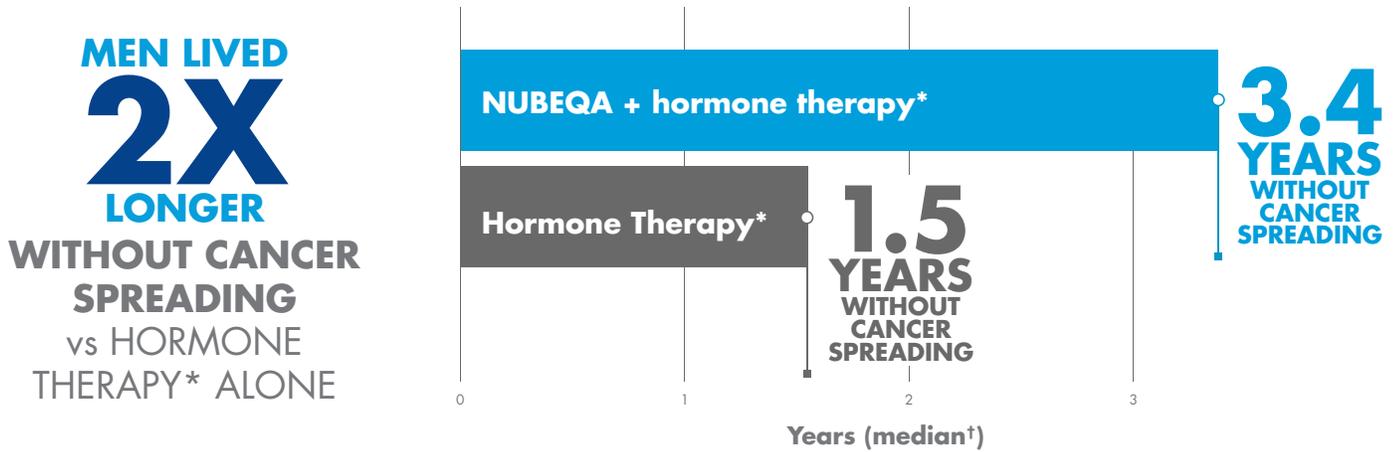
Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).


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PROVEN RESULTS WITH NUBEQA® IN nmCRPC

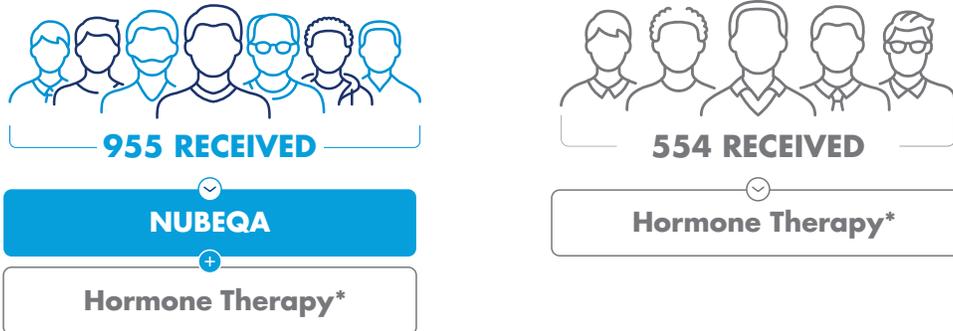
Proven results in non-metastatic castration-resistant prostate cancer (nmCRPC)

In a clinical study, men treated with NUBEQA lived longer without their cancer spreading



Men with nmCRPC who were treated with NUBEQA and hormone therapy* lived more than twice as long without their cancer spreading to other parts of the body, compared with men who only received hormone therapy (median† 3.4 years vs 1.5 years).

How NUBEQA was studied in nmCRPC



A clinical study of 1509 men with nmCRPC compared NUBEQA + hormone therapy with hormone therapy* alone.

[SEE SIDE EFFECTS IN nmCRPC](#)

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

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

IMPORTANT SAFETY INFORMATION

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

- decreased red blood cells (anemia)
- decreased white blood cells
- high blood sugar levels

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).


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PROVEN RESULTS WITH NUBEQA® IN nmCRPC

Proven results in **non-metastatic castration-resistant prostate cancer (nmCRPC)**

In the same study, NUBEQA also helped men live longer

31% lower risk of death
with **NUBEQA** ↓

Men with nmCRPC who were treated with NUBEQA + hormone therapy* had a 31% lower risk of dying than men on hormone therapy alone.

Another way to look at results:

In the study for nmCRPC, more men treated with NUBEQA + hormone therapy* were alive at 3 years

- 83% of men who are still alive with NUBEQA + hormone therapy*
- 77% of men were still alive with hormone therapy* alone

SEE SIDE EFFECTS IN nmCRPC ▶

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

IMPORTANT SAFETY INFORMATION (continued)

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

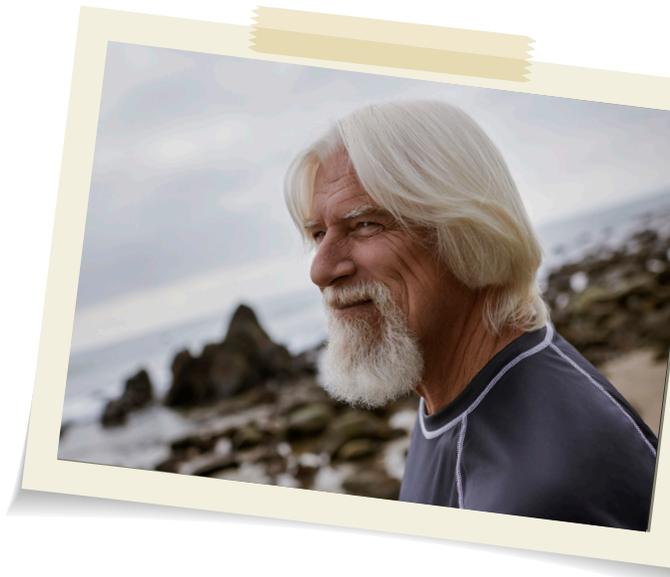
- increase in liver function tests
- low blood calcium levels

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 the FDA at 1-800-FDA-1088.

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).




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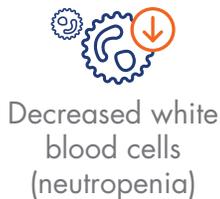
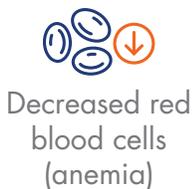
SIDE EFFECTS IN mHSPC

Side effects in metastatic hormone-sensitive prostate cancer (mHSPC)

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 men with mHSPC experienced when treated with the NUBEQA combination* include:



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.

*NUBEQA combination=NUBEQA + hormone therapy and docetaxel (chemotherapy).

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

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).



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SIDE EFFECTS IN nmCRPC

Side effects in non-metastatic castration-resistant prostate cancer (nmCRPC)

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 men with nmCRPC experienced when treated with NUBEQA + hormone therapy* include:



Increase in liver function tests



Decreased white blood cells (neutropenia)



Feeling more tired than usual



Arm, leg, hand, or foot pain



Rash

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.

*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 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

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).


NUBEQA[®]
(darolutamide) 300 mg tablets

HOW TO TAKE NUBEQA®

Follow your doctor's instructions while taking NUBEQA

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 breastmilk

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.

Do not start or stop any medicine before talking with the healthcare provider that prescribed you NUBEQA.

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.

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NUBEQA[®]
(darolutamide) 300 mg
tablets

HOW TO TAKE NUBEQA®

Follow your doctor's instructions while taking NUBEQA

2 TABLETS TWICE A DAY WITH FOOD



TAKING NUBEQA

- Take your prescribed dose of NUBEQA 2 times a day with food
- Swallow NUBEQA tablets whole
- Your healthcare provider may change your dose, temporarily stop, or completely stop your treatment with NUBEQA if you have certain side effects
- 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
- If you take more NUBEQA than prescribed, call your healthcare provider right away
- 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)
- Take NUBEQA exactly as your healthcare provider tells you

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
- **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

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).


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(darolutamide) 300 mg
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HOW TO TAKE NUBEQA®

Follow your doctor's instructions while taking NUBEQA

HOW THE NUBEQA COMBINATION* IS GIVEN TO MEN WITH mHSPC

NUBEQA is **not chemotherapy**, but it is approved in combination with a chemotherapy called docetaxel for the treatment of **metastatic hormone-sensitive prostate cancer (mHSPC)**.



- Your doctor should start your treatment with docetaxel within the first 6 weeks of starting NUBEQA
- Docetaxel is given once every 3 weeks (21 days) as an intravenous (IV) infusion in your arm for a total of up to 6 treatment cycles (approximately 5 months)
- Your doctor may change, delay, or stop treatment with docetaxel if needed
- Treatment with NUBEQA can continue after completing chemotherapy as prescribed by your doctor

*NUBEQA combination=NUBEQA + hormone therapy with docetaxel (chemotherapy).

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

IMPORTANT SAFETY INFORMATION (continued)

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

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

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).


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Talk to your **healthcare provider** to see if
NUBEQA may be right for you

SUPPORT & RESOURCES

Support for you while taking NUBEQA®

Access Services by Bayer™ 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 \$0 Co-Pay Program.



Enroll online ▶

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](https://www.medicare.gov/your-medicare-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
1-800-675-8416

IF YOU DO NOT HAVE INSURANCE

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

Please contact the program at 1-866-228-7723 Monday-Friday, 9 AM - 6 PM (ET), or visit the foundation website at www.patientassistance.bayer.us for information or to see if you qualify for assistance.

Depending on insurance plans and other factors, the cost of NUBEQA may differ from person to person. How much you will pay depends on your insurance coverage. To learn about your insurance coverage and paying for NUBEQA, call a specialist at Access Services by Bayer.

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.

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).


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SUPPORT & RESOURCES

Resources for patients and caregivers

Organizations offering more support for men with prostate cancer and their loved ones

CANCER ABCs™
www.cancerabcs.org
1-516-445-2026

CancerCare®
www.cancercares.org
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
1-800-757-2873

PROSTATE CANCER
INTERNATIONAL (PCaI)
www.pcainternational.org
www.prostatecancerinfolink.net

PROSTATE CANCER RESEARCH
INSITUTE (PCRI)
www.pcri.org

ZERO PROSTATE CANCER
www.zerocancer.org
1-202-463-9455

PROSTATE HEALTH EDUCATION
NETWORK (PHEN)
www.prostateheathed.org
1-202-463-9455

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

More information is available online



Visit NUBEQA Site ▶

Stories from men taking NUBEQA and their caregivers



Watch Video ▶

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 may report side effects to the FDA at 1-800-FDA-1088.

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages **18-19**, and the full **Prescribing Information**.


NUBEQA[®]
(darolutamide) 300 mg
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IMPORTANT FACTS ABOUT NUBEQA® (darolutamide) tablets

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 (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 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.

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

Please see additional Important Safety Information throughout, Important Facts about NUBEQA on pages [18-19](#), and the full [Prescribing Information](#).



NUBEQA[®]
(darolutamide) 300 mg tablets

IMPORTANT FACTS ABOUT NUBEQA® (darolutamide) tablets

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.

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

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

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.





NUBEQA[®] HELPS YOU LIVE FOR WHAT YOU LOVE

The NUBEQA clinical study in patients with **nmCRPC**^{*} was designed to measure metastasis-free survival (MFS) and also overall survival (OS). Men with nmCRPC who took NUBEQA + hormone therapy[†] lived more than twice as long without prostate cancer spreading to other parts of their body compared with men on hormone therapy alone (median[‡] 3.4 years vs 1.5 years). NUBEQA extended OS by lowering the risk of death by 31% compared with hormone therapy[†] alone.

The clinical study for NUBEQA in **mHSPC**[§] was designed to measure OS. NUBEQA extended OS by lowering the risk of death by 32% compared with docetaxel + hormone therapy[†] alone.

*nmCRPC=non-metastatic castration-resistant prostate cancer.

†Hormone therapy includes drug treatments or surgery to lower testosterone.

‡Median is the middle number in a set of values, not the average.

§mHSPC=metastatic hormone-sensitive prostate cancer.

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**), 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 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)
- have a history of seizures, brain injury, stroke, or brain tumors
- have kidney or liver problems



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NUBEQA[®]
(darolutamide) 300 mg
tablets