

ABOUT NUBEQA[®]

(darolutamide)

YOUR GUIDE TO TREATMENT

This booklet is intended for patients who
have been prescribed Nubeqa

For more information please refer to the package leaflet

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at

<https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

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has been developed
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ORION
PHARMA



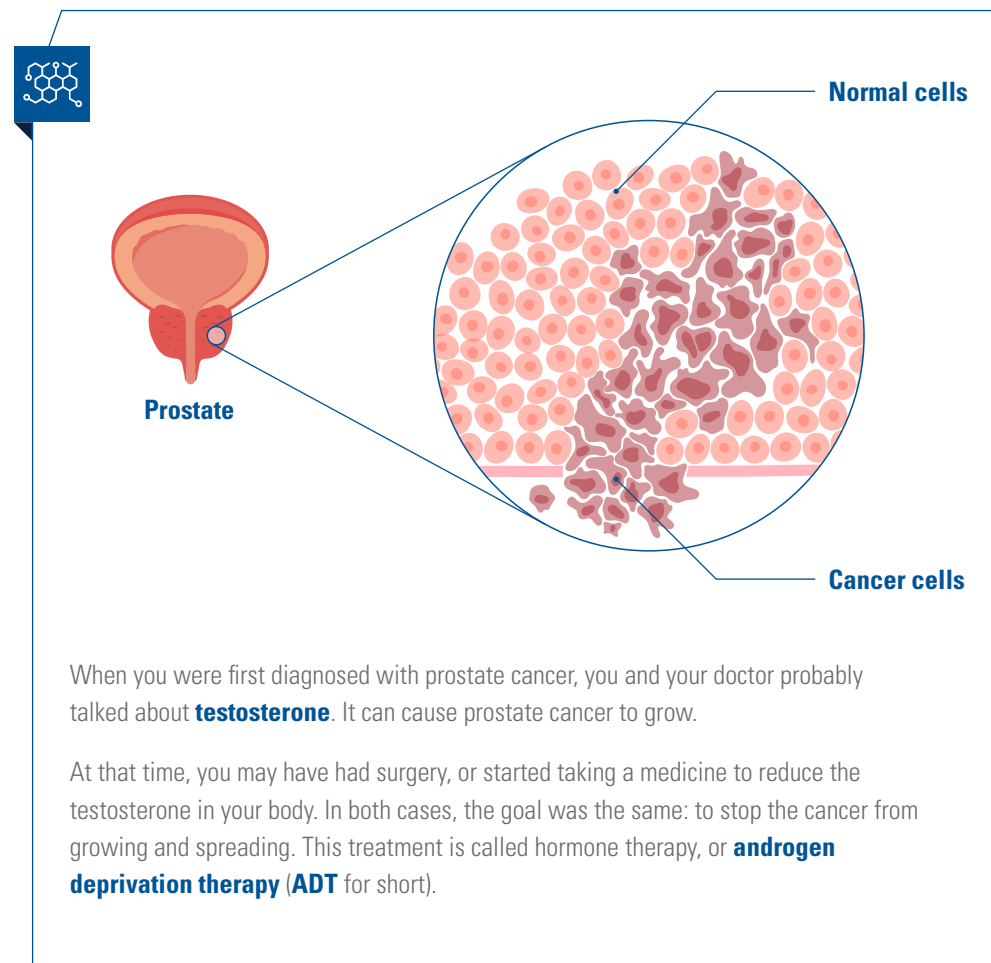

NUBEQA[®]
(darolutamide) 300 mg
tablets

CONTENTS:

What is prostate cancer?	3
Understanding your diagnosis	4
Taking action with NUBEQA	6
What should I know about side effects?	8
How do I take NUBEQA?	12
Important things to keep in mind	15
Additional information and support	16
What should I discuss with my doctor?	17
Caring for someone with prostate cancer	18
My healthcare team	19
Glossary	20
Notes	21

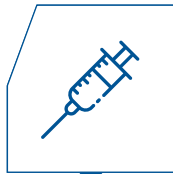
WHAT IS PROSTATE CANCER?

Cancer develops when the body's normal process of cell regeneration is disrupted, allowing cells to grow unchecked, and forming a lump or **tumour**. If this starts in your prostate, a small gland just beneath your bladder, it would be referred to as **prostate cancer**.



UNDERSTANDING YOUR DIAGNOSIS

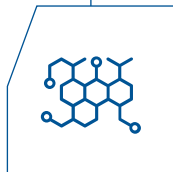
When you were diagnosed, your doctor may have given you a series of tests designed to learn more about the cancer and how it is affecting your body.



These may have included a test to measure the level of **prostate specific antigen (PSA)**, in your blood. This can help determine not only whether you may have prostate cancer, but also how well your existing treatments are working.



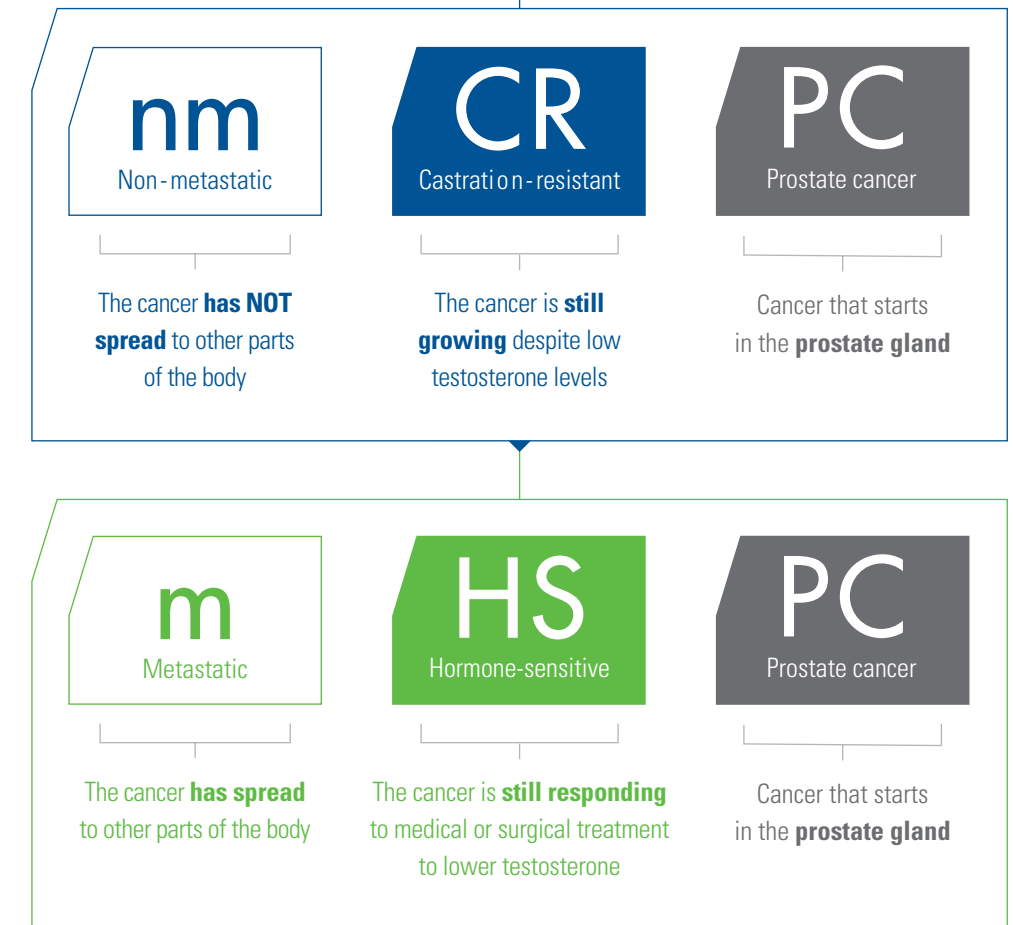
Consecutive rises in PSA levels, despite treatment such as ADT, can be an early sign of advanced prostate cancer. Sometimes, this is followed by the spread of the cancer beyond the prostate to other organs.



Cancer that has spread is called **metastatic**. Metastatic prostate cancer is also known as **advanced prostate cancer**. If the cancer has NOT spread to other parts of the body, it is **non-metastatic (nm)**.



If you have been recommended NUBEQA, you will have one of the following diagnoses:



TAKING ACTION WITH NUBEQA

NUBEQA is a tablet that you take alongside your existing prostate cancer treatments. It contains the medicine darolutamide, which is used to treat patients with nmCRPC who are at high risk of developing metastatic disease or with mHSPC.

NUBEQA

NUBEQA is a treatment for prostate cancer that works by blocking the cancer cell's ability to respond to testosterone, and helping to delay cancer cell growth.

For patients with nmCRPC, this could mean helping to delay the spread of the cancer outside of the prostate. In patients with mHSPC, NUBEQA may help to delay further growth.



ADT

Hormone therapy, also called androgen deprivation therapy (**ADT**), helps to lower testosterone levels, to prevent the prostate cancer from growing or spreading. NUBEQA works in combination with your ADT, helping to reduce the effect of testosterone on cancer cells.



Chemotherapy

For patients with mHSPC only, NUBEQA can be used **with** or **without** chemotherapy, which is sometimes referred to as docetaxel. This treatment also helps to stop the growth and spread of cancer cells.

Your doctor will discuss with you whether or not you will receive chemotherapy alongside ADT and NUBEQA. If you do receive chemotherapy, you will receive up to 6 cycles of chemotherapy, over approximately 4 months, or 18 weeks.



ARE THERE SIDE EFFECTS?

All treatments have side effects, including NUBEQA, although not everyone gets them. You can learn more about side effects associated with taking NUBEQA on **pages 8 to 10**, or in your patient information leaflet.

IF YOU HAVE ANY QUESTIONS FOR YOUR DOCTOR, YOU CAN WRITE THEM DOWN IN THE NOTES SECTION ON PAGE 21.

WHAT SHOULD I KNOW ABOUT **SIDE EFFECTS**?

All treatments have side effects, although not everyone gets them. Below are the most common side effects that have been reported. However, you may experience others while on NUBEQA.



MOST FREQUENT EFFECTS IN nmCRPC:

More than **1** out of **10**



Tiredness (fatigue)

Up to **1** in **10**



Pain in arms and legs



Rash



Bone fractures



Heart disease or failure

In addition, very common side effects (**more than 1 in every 10 people**) that may show up in blood tests are:

- **A reduced number of a white blood cell type called neutrophils**, which could raise the risk of getting an infection
- **High blood levels of substances produced by the liver** (bilirubin, alanine transaminase and aspartate transaminase) – these indicate a change to liver function
- **Anaemia** – due to a reduced number of red blood cells

PLEASE SEE YOUR PATIENT INFORMATION LEAFLET FOR A FULL LIST OF ADVERSE EVENTS.

If you experience any of the adverse events listed above, please discuss this with your doctor. They may be able to help you manage them and give advice on lifestyle changes that could reduce their effect.



MOST FREQUENT EFFECTS IN mHSPC:

Patients who receive NUBEQA together with **ADT** and **docetaxel**

More than **1** out of **10**



Rash



High blood pressure

In addition, very common side effects (**more than 1 in every 10 people**) that may show up in blood tests are:

- **High level of substances produced by the liver in the blood** (bilirubin, alanine aminotransferase and aspartate transaminase) – these indicate a change to liver function

Patients who receive NUBEQA **with ADT** but **without docetaxel**

More than **1** out of **10**



Tiredness (fatigue)

Up to **1** in **10**



Pain in arms and legs



Rash



Bone fractures



Heart disease or failure

In addition, very common side effects (**more than 1 in every 10 people**) that may show up in blood tests are:

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- **Anaemia** – due to a reduced number of red blood cells

You should contact your doctor immediately if you experience any of the following serious side effects:

- Chest pain, pain in other parts of the body (spreading from your chest to your arms, jaw, neck, back and tummy), feeling lightheaded or dizzy, sweating, shortness of breath, feeling sick (signs of heart disease caused by blockage of the blood vessels in the heart).
- Breathlessness after activity or at rest, tiredness most of the time, feeling lightheaded or fainting and swelling of the ankles and legs (signs of heart failure).
- Seizures

Please contact your doctor if you have any of the following symptoms that are occasionally related to signs of liver injury and do not go away or keep coming back over time:

- feeling sick (nausea)
- vomiting
- abdominal discomfort
- yellowing of the skin or eyes
- darkening of the urine
- loss of appetite



AN IMPORTANT NOTE ON FERTILITY AND PREGNANCY

Please be aware that NUBEQA could reduce male fertility. The following advice should be followed while taking and 1 week after stopping NUBEQA:

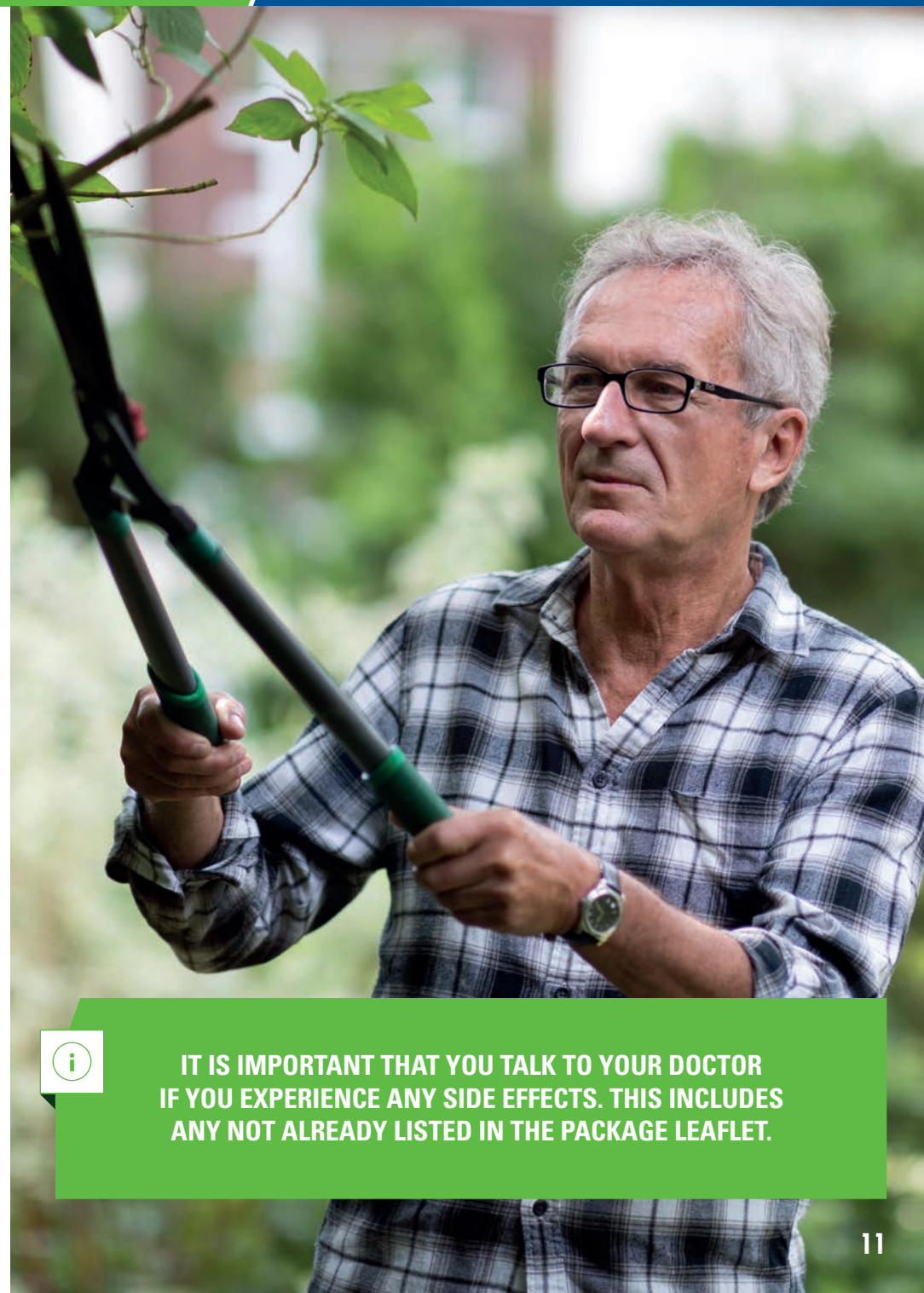
- Use a condom or another highly effective method of birth control to prevent pregnancy, if you are having sex with a woman who can become pregnant
- Use a condom to protect the unborn baby, if you are having sex with a pregnant woman

Talk to your doctor if you have concerns.

REPORTING SIDE EFFECTS

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not mentioned in this or any other leaflet given to you by a doctor.

You can also report side effects directly via the Yellow Card Scheme (as detailed on the front cover). By reporting side effects, you can help provide more information on the safety of this medicine. Visit <https://yellowcard.mhra.gov.uk/>



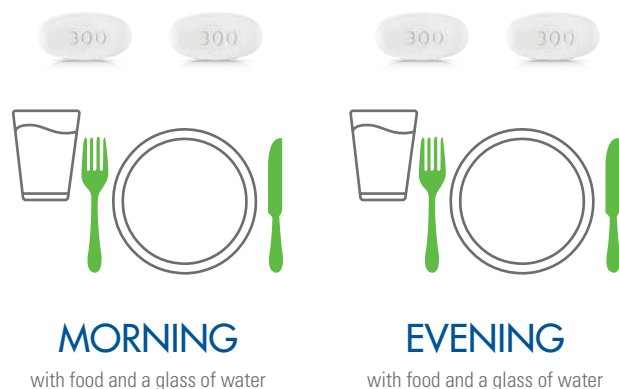
IT IS IMPORTANT THAT YOU TALK TO YOUR DOCTOR IF YOU EXPERIENCE ANY SIDE EFFECTS. THIS INCLUDES ANY NOT ALREADY LISTED IN THE PACKAGE LEAFLET.

HOW DO I TAKE NUBEQA?

You should take NUBEQA as your doctor has told you. This normally means:

**2 TIMES A DAY
WITH FOOD
AND A GLASS
OF WATER**

Pills not actual size.



- The recommended dose of NUBEQA is **600 mg** (two 300 mg tablets) swallowed whole and taken twice each day. **Do not chew or break up the tablets. Do not take more than 4 tablets per day**
- Your doctor may change your dose if needed. Do not stop taking your prescribed dose of NUBEQA without talking to your doctor first



DO I CONTINUE MY EXISTING PROSTATE CANCER TREATMENTS?

You should continue ADT during your treatment with NUBEQA unless you've had surgery to lower the amount of testosterone in your body (surgical castration). Discuss this with your doctor.

If you have been diagnosed with mHSPC, you may or may not also receive up to 6 cycles of chemotherapy (docetaxel) alongside NUBEQA.

WHAT SHOULD I DO IF I MISS A DOSE?

Take your missed dose with food 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

STAY ON SCHEDULE

To get the most benefit from NUBEQA, it is important that you stay on schedule with your treatments and keep your appointments. If you cannot keep an appointment, make sure you give your doctor as much notice as possible.

WHAT IF I'VE HAD A SEIZURE, OR A PROBLEM WITH MY KIDNEYS, LIVER AND/OR HEART?

Be sure to inform your doctor, as this may impact your suitability for NUBEQA or the dose.



I'M ON OTHER MEDICATION, DOES THIS MATTER?

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines may influence the effect of NUBEQA, or NUBEQA may influence the effect of these medicines. These medicines are typically used to treat:



Serious bacterial infections:
rifampicin



Epilepsy, such as **carbamazepine**,
phenobarbital, **phenytoin**



High cholesterol, such as
rosuvastatin, **fluvasatin**,
atorvastatin, **pitavastatin**



Slightly low mood and mild
anxiety: **St. John's Wort** (a herbal
medicine)



Severe joint inflammation, severe
cases of the skin disease psoriasis,
and cancers: **methotrexate**



Inflammatory bowel diseases:
sulfasalazine

Your doctor may therefore change the dose of the medicines you are taking.

FOOD INTOLERANCES

NUBEQA contains **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.



IMPORTANT THINGS TO KEEP IN MIND



Reach out to your loved ones or your doctor if you need support.



Learn more about your diagnosis – take time to understand what your diagnosis means for you and what treatment options are available to you



Build routines – sometimes it can be difficult for a person to make the necessary changes to their diet or exercise routine. Changing routines gradually may help



Find a support group – often it can help you and your loved ones to know that you are not alone. Support groups offer a sense of community while you are on this journey

ADDITIONAL INFORMATION AND SUPPORT

ABOUT NUBEQA

PATIENT PACKAGE LEAFLET

See the patient leaflet for all important information about NUBEQA. You can get this from your doctor, pharmacist, or at www.medicines.org.uk

ABOUT PROSTATE CANCER

ORCHID

Offers a helpline and website support:
orchid-cancer.org.uk

TACKLE PROSTATE CANCER

Runs a network of prostate cancer support groups:
tackleprostate.org

NHS

Offers an overview of the symptoms, causes, diagnosis, PSA testing and treatments:
www.nhs.uk

PROSTATE CANCER UK

Has a number of educational guides and support materials that you can download:
www.prostatecanceruk.org

CANCER RESEARCH UK

Provides lots of in-depth information about the disease and treatments:
www.cancerresearchuk.org

ABOUT CAREGIVER SUPPORT

MACMILLAN UK

A list of cancer types A to Z, as well as providing important information for people supporting someone with cancer:
www.macmillan.org.uk

WHAT SHOULD I DISCUSS WITH MY DOCTOR?

Take a minute to consider and review these areas of your life. Your doctor may ask about these at your next appointment so that you can discuss how NUBEQA will fit into your current lifestyle.

You can make notes below the question or in the notes section on [page 21](#).



Sleep patterns:

Do you typically sleep well?



Appetite:

What kind of food do you normally eat and when?



Exercise:

How often do you exercise and how?



Medicines:

What other medications are you taking?



Mental health:

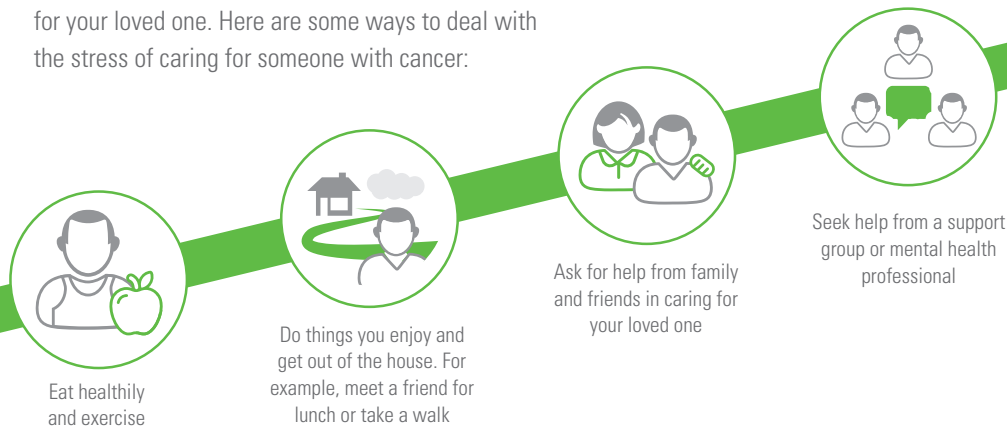
How are you coping? Do you feel anxious, isolated or lonely?

CARING FOR SOMEONE WITH PROSTATE CANCER

HOW TO LOOK AFTER YOURSELF

The role of carer can be challenging. You may feel angry, sad and overwhelmed and these feelings can affect you in many ways. You may have trouble sleeping or feel more tired than usual. It's important to pay attention to your own health and to care for yourself as well.

Taking care of yourself will help you provide the best possible support for your loved one. Here are some ways to deal with the stress of caring for someone with cancer:



HOW YOU CAN MAKE A DIFFERENCE

- Be guided by the person you're caring for. Modifying things at home to make daily tasks more manageable can be a good idea. Before you do that, be sure that the person you're caring for will welcome and benefit from that kind of intervention.
- Help manage medications. Something as simple as setting a reminder or alarm on your phone for when medicines are due can help prevent missed doses.
- Encourage visitors. Sometimes living with prostate cancer starts to inhibit the social life of the person you're caring for and they can feel isolated. If you notice this, invite and encourage friends and family to visit at home.

MY HEALTHCARE TEAM

Medical Oncologist

Name _____ Phone # _____

Email _____

Urologist

Name _____ Phone # _____

Email _____

Radiation Oncologist

Name _____ Phone # _____

Email _____

General Practitioner

Name _____ Phone # _____

Email _____

Nurse

Name _____ Phone # _____

Email _____

Pharmacy

Name _____ Phone # _____

Email _____

GLOSSARY

Advanced prostate cancer:

Prostate cancer that has spread beyond the prostate to other parts of the body. Often follows an increase in PSA levels. Also called metastatic prostate cancer.

Androgen deprivation therapy (ADT):

Medicine or surgery to reduce testosterone levels and delay the spread of prostate cancer.

Castration-resistant (CR):

Prostate cancer that grows or spreads despite lowered testosterone levels.

Docetaxel:

A form of chemotherapy designed to kill quickly dividing cancer cells. You may or may not receive this alongside NUBEQA if you have been diagnosed with mHSPC.

Hormone-sensitive (HS):

Cancer that still responds to testosterone-lowering treatments.

Metastatic (m):

Cancer that has spread to other parts of the body.

Non-metastatic (nm):

Cancer that has not spread to other places from its original location in the body.

Prostate cancer (PC):

Cancer that started in the prostate gland.

Prostate-specific antigen (PSA):

A protein found in the blood. It is used to track changes in prostate cancer.

Testosterone:

An androgen-type hormone that can cause prostate cancer to grow and spread.

NOTES

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NOTES



**IF YOU HAVE ANY QUESTIONS, OR NEED
MORE INFORMATION, TALK TO YOUR DOCTOR.**

Provided as a service to medicine by Bayer and Orion Pharma.

For further information about NUBEQA please contact Bayer at:

Bayer plc, 400 South Oak Way, Reading, Berkshire, RG2 6AD, United Kingdom. Tel: 0118 206 3000.

For any medical information requests, please contact: medical.information@bayer.co.uk

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NUBEQA®
(darolutamide) 300 mg
tablets