

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects that you may experience with this medicine. See the [full CMI](#) for further details.

1. WHY AM I USING NUBEQA?

NUBEQA contains the active ingredient darolutamide. **NUBEQA is used to treat prostate cancer that has not spread to other parts of the body** and no longer responds to medical or surgical treatment that lowers testosterone. In combination with docetaxel, **NUBEQA is used to treat prostate cancer that has spread to other parts of the body** and responds to medical or surgical treatments that lower testosterone.

For more information, see Section [1. Why am I using NUBEQA?](#) in the full CMI.

2. What should I know before I use NUBEQA?

Do not use if you have ever had an allergic reaction to NUBEQA or any of the ingredients listed at the end of the CMI.

NUBEQA is not for use in women.

Do not use NUBEQA if you are intending to father a child. Use a highly effective method of contraception during and for 3 months after treatment with NUBEQA.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use NUBEQA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NUBEQA and affect how it works. Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take NUBEQA?

- **The recommended dose is two tablets two times a day.** This is also the maximum daily dose.
- Your doctor may need to reduce your dose to one tablet two times daily or may decide to interrupt your treatment if necessary.
- Your doctor may prescribe other medicines while you are taking NUBEQA.
- You may also receive docetaxel. Your doctor will tell you how and when you will get it.
- Take NUBEQA with food.
- Swallow the tablets whole

More instructions can be found in Section [4. How do I use NUBEQA?](#) in the full CMI.

5. What should I know while using NUBEQA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using NUBEQA. • Talk to your doctor if you have a history of seizure, or have any other medical condition
Things you should not do	• Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	• There is no evidence that NUBEQA will affect your ability to drive or use machines.
Looking after your medicine	• Follow the instruction in the carton on how to take care of your medicine properly. • Store it in a cool dry place away from moisture, heat or sunlight

For more information, see Section [5. What should I know while using NUBEQA?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, NUBEQA can cause side effects, although not everybody gets them. The most common side effects are fatigue, rash, hypertension, constipation, decreased appetite and pain in the extremity (pain in the arms and legs). For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems. [Include if applicable]

NUBEQA®

Active ingredient(s): *darolutamide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NUBEQA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NUBEQA**

Where to find information in this leaflet:

1. [Why am I using NUBEQA?](#)
2. [What should I know before I use NUBEQA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use NUBEQA?](#)
5. [What should I know while using NUBEQA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using NUBEQA?

NUBEQA contains the active ingredient darolutamide.

Darolutamide is an androgen receptor inhibitor. It works by blocking the activity of male sex hormones called androgens, such as testosterone leading to inhibition of growth and division of prostate cancer cells. By blocking these hormones, darolutamide stops prostate cancer cells from growing and dividing.

NUBEQA is used to treat 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**)

In combination with docetaxel, **NUBEQA is used to treat prostate cancer that has spread to other parts of the body** and responds to medical or surgical treatments that lower testosterone (metastatic hormone sensitive prostate cancer or **mHSPC**).

2. What should I know before I use NUBEQA?

Warnings

Do not use NUBEQA if:

- you are allergic to darolutamide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You are intending to father a child. Use a highly effective method of contraception during and for 3

months after treatment with NUBEQA to prevent pregnancy.

Check with your doctor if you:

- have high blood pressure,
- have a history of seizure, or
- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy, fertility and breastfeeding

NUBEQA is not for use in women.

Do not take NUBEQA if you are pregnant, are breast-feeding or may be potentially pregnant.

This medicine could possibly have an effect on male fertility.

If you are having sex with a woman of childbearing age, you are advised to use a highly effective method of contraception during and for 3 months after treatment with NUBEQA to prevent pregnancy.

If you are having sex with a pregnant woman, you are advised to use a condom during and for 3 months after treatment with NUBEQA to protect the unborn baby.

Children and adolescents

- The safety and efficacy in children and adolescents under 18 years of age have not been studied.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NUBEQA and affect how it works, or NUBEQA may influence the effect of these medicines:

- rifampicin – typically used to treat bacterial infections
- carbamazepine, phenobarbital – typically used to treat epilepsy
- St. John's Wort – typically used to treat symptoms of slightly low mood and mild anxiety
- rosuvastatin, fluvastatin, atorvastatin – typically used to treat high cholesterol

- methotrexate – typically used to treat severe joint inflammation, severe cases of the skin disease psoriasis, and cancers
- sulfasalazine – typically used to treat inflammatory bowel disease

The dose of other medicines that you are taking may need to be changed

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NUBEQA.

4. How do I take NUBEQA?

How much to take

- **The recommended dose** is two tablets two times a day. This is also the maximum daily dose.
- Your doctor may need to reduce your dose to one tablet two times daily or may decide to interrupt your treatment if necessary.
- **The recommended starting dose** if you have a moderately impaired liver function or severely impaired kidney function, is one tablet two times daily.
- No dose adjustment is necessary if you have mildly impaired liver function.
- No dosage adjustment is necessary if you have mildly or moderately impaired kidney function

How to take NUBEQA

- Your doctor may prescribe other medicines while you are taking NUBEQA.
- You may also receive docetaxel. Your doctor will tell you how and when you will get it.
- NUBEQA should be taken with food
- Swallow the tablets whole
- Always take this medicine exactly as your doctor or pharmacist has told you.

If you forget to use NUBEQA

NUBEQA should be taken regularly at the same time each day. If you miss your dose at the usual time, take your missed dose as soon as you remember prior to the next scheduled dose.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much NUBEQA

If you think that you have used too much NUBEQA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26 for Australia**), or
- by calling **0800 POISON (0800 764 766 for New Zealand)**, or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using NUBEQA?

Things you should do

- If you are having sex with a woman of childbearing age you are advised to use a highly effective method of contraception during and for 3 months after treatment with NUBEQA to prevent pregnancy.
- If you are having sex with a pregnant woman you are advised to use a condom during and for 3 months after treatment with NUBEQA to protect the unborn baby.
- Remind any doctor, dentist or pharmacist you visit that you are using NUBEQA.

Things you should not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Driving or using machines

There is no evidence that NUBEQA will affect your ability to drive or use machines.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

BOTTLE: Once bottle is opened the medicine is stable for 3 months. Keep the bottle tightly closed after first opening.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
Patients with non-metastatic castration resistant prostate cancer • Fatigue (tiredness) • Rash • Pain in the extremity (pain in arms and legs) Patients with metastatic hormone sensitive prostate cancer • Constipation • decreased appetite • rash • weight increase • haemorrhage • pain in extremity • hypertension (high blood pressure)	Speak to your doctor if you have any of these side effects and they worry you.
Serious side effects	What to do
• pressure or pain in your chest or arms that may spread to neck, jaw or back, • chest pain or discomfort or shortness of breath at rest or with activity, • changes in heart rate, • dizziness or lightheadedness, • nausea, vomiting • yellowing of the skin or eyes, • darkening of the urine	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

NUBEQA may cause abnormal blood test results. This includes abnormal blood cell counts, blood sugar and liver enzymes.

Your doctor will decide when to perform blood tests and will interpret the results.

If your blood tests show abnormal results of your liver function, your doctor may decide to stop treatment permanently.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems (Australia) or at <https://pophealth.my.site.com/carmreportnz/s/> (New Zealand). By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NUBEQA contains

Active ingredient (main ingredient)	darolutamide
Other ingredients (inactive ingredients)	• calcium hydrogen phosphate dihydrate • croscarmellose sodium • hypromellose • lactose monohydrate • macrogol 3350 • magnesium stearate • povidone • titanium dioxide
Potential allergens	Lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What NUBEQA looks like

The film-coated tablets are white to off-white, oval with a length of 16 mm and a width of 8 mm. They are marked with "300" on one side, and "BAYER" on the other side.

Registration number

- Blister AUST R 316417 (Australia)
- Bottle AUST R 317242 (Australia)
- TT50-10967 (New Zealand)

Who distributes NUBEQA

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Bayer New Zealand Ltd
PO Box 2825
Shortland Street
Auckland 1140

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information

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