EMA/57487/2023
EMEA/H/C/004790

Nubeqa (*darolutamide*)

An overview of Nubeqa and why it is authorised in the EU

What is Nubeqa and what is it used for?

Nubeqa is a medicine used to treat men with prostate cancer.

It is used when the cancer is castration-resistant (worsens despite treatment to lower testosterone levels, including surgical removal of the testes) and is at high risk of metastasis (spreading to other parts of the body).

It is also used when the cancer has spread to other parts of the body but responds to treatment that lowers testosterone levels (hormone sensitive). It is used in combination with a treatment called androgen deprivation therapy (treatment to lower male sex hormones) with or without docetaxel (another cancer medicine).

Nubeqa contains the active substance darolutamide.

How is Nubeqa used?

Nubeqa can only be obtained with a prescription and treatment should be started and supervised by a specialist doctor experienced in the treatment of prostate cancer.

Nubeqa is available as tablets to be taken twice a day with food.

Patients who have not had their testes surgically removed (castration) should continue treatment with a medicine known as an LHRH agonist or LHRH antagonist to lower production of testosterone.

If the patient develops severe side effects, the dose may have to be reduced or treatment may have to be interrupted.

For more information about using Nubeqa, see the package leaflet or contact your doctor or pharmacist.

How does Nubeqa work?

The active substance in Nubeqa, darolutamide, is an androgen receptor inhibitor. This means that it binds to the receptor (target) of sex hormones called androgens, such as testosterone, and blocks them from stimulating the growth of prostate cancer cells.

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What benefits of Nubeqa have been shown in studies?

Nubeqa was compared with placebo (a dummy treatment) in a main study involving 1,509 men with non-metastatic prostate cancer. The main measure of effectiveness was how long patients lived before their cancer spread to other parts of the body. Patients treated with Nubeqa lived for an average of 40 months without the cancer spreading, compared with around 18 months for patients given placebo.

In a second main study involving 1,306 men with metastatic, hormone-sensitive prostate cancer, around 63% of patients given Nubeqa were alive 4 years after starting treatment compared with 50% of those who were given placebo. Both Nubeqa and placebo were given together with docetaxel and androgen deprivation therapy.

In a third main study involving 669 men with metastatic, hormone-sensitive prostate cancer, Nubeqa was effective at delaying worsening of the disease. After 3 years of treatment, the cancer did not get worse in 71% of patients receiving Nubeqa compared with 58% of those given placebo. The average period before the disease got worse in patients given placebo was 25 months; for those who received Nubeqa, this figure could not be calculated as not enough people had experienced worsening of their disease. Both Nubeqa and placebo were given together with androgen deprivation therapy.

What are the risks associated with Nubeqa?

For the complete list of side effects and restrictions with Nubeqa, see the package leaflet.

The most common side effects with Nubeqa (which may affect more than 1 in 10 people) are tiredness, weakness, lethargy (lack of energy) and feeling unwell.

The most common side effects with Nubeqa given together with docetaxel (which may affect more than 1 in 10 people) are rash and hypertension (high blood pressure).

Nubeqa is not for use in women and must not be used in women who are or who may be pregnant. For the full list of restrictions, see the package leaflet.

Why is Nubeqa authorised in the EU?

Nubeqa has been shown to delay disease progression in men with prostate cancer compared with placebo. When given together with docetaxel and androgen deprivation therapy, the medicine has been shown to increase the time patients with metastatic hormone-sensitive prostate cancer live. Nubeqa is well tolerated and its risks are considered manageable. The European Medicines Agency therefore decided that Nubeqa's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Nubeqa?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Nubeqa have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Nubeqa are continuously monitored. Side effects reported with Nubeqa are carefully evaluated and any necessary action taken to protect patients.

Other information about Nubeqa

Nubeqa received a marketing authorisation valid throughout the EU on 27 March 2020.

Further information on Nubeqa can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/nubeqa.

This overview was last updated in 07-2025.