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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).

Nubeqa contains the active substance darolutamide.

How is Nubeqa used?

Nubeqa is available as tablets (300 mg) and can only be obtained with a prescription. Treatment should be started and supervised by a specialist doctor experienced in the treatment of prostate cancer.

The recommended dose of Nubeqa is 600 mg (two tablets) 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 analogue' 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 prostate cancer cells from growing.

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What benefits of Nubeqa have been shown in studies?

Nubeqa was compared with placebo (a dummy treatment) in one ongoing main study in 1,509 men with non-metastatic cancer of the prostate.

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.

What are the risks associated with Nubeqa?

The most common side effects with Nubeqa (which may affect more than 1 in 10 patients) are tiredness, weakness, lethargy (lack of energy), feeling unwell, decreased neutrophil count (a type of white blood cell that fights infection), increased blood levels of bilirubin (a breakdown product of red blood cells made in the liver, indicating liver problems) and certain liver enzymes (aspartate aminotransferase). For the full list of side effects of Nubeqa, see the package leaflet.

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?

The European Medicines Agency decided that Nubeqa's benefits are greater than its risks and it can be authorised for use in the EU. Nubeqa has been shown to delay the onset of metastases compared with placebo. It is also well tolerated and its risks are considered manageable.

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

The company that markets Nubeqa has been requested to provide the final results of the main study once completed.

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/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 03-2020.