

Public Summary SwissPAR vom 12.04.2021

## Nubeqa<sup>®</sup> (active substance: darolutamide)

First authorisation in Switzerland: 19 June 2020

Medicinal product (film-coated tablets) for the treatment of adult male patients with non-metastatic castration-resistant prostate cancer in combination with androgen suppression therapy.

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### About the medicine

The medicinal product Nubeqa contains the active substance darolutamide. Nubeqa is used for androgen suppression therapy, which reduces the production of sex hormones, including testosterone.

It was authorised for the treatment of adult male patients with non-metastatic castration-

resistant prostate cancer in combination with androgen suppression therapy (AST). This is a type of prostate cancer with a high risk of forming metastases, meaning that it spreads to other tissues or organs in the body.

In castration-resistant prostate cancer, the cancer continues to grow in spite of treatment to reduce testosterone in the body.

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### Mode of action

Darolutamide, the active substance in Nubeqa, is an androgen receptor inhibitor. An androgen receptor inhibitor prevents certain sex hormones, including testosterone, from bind-

ing to certain proteins known as androgen receptors. This blocks the action of these hormones on the body, which can stop or slow the growth of the prostate cancer cells.

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### Use

Nubeqa is a prescription-only medicine. The recommended dose of Nubeqa is 600 mg twice a day. The medicine should be swallowed whole and taken at the same time as a meal. If the patient experiences serious side effects, treatment can be stopped or reduced to 300 mg twice a day until the symptoms improve.

Patients taking Nubeqa should take a gonadotropin releasing hormone analogue (a synthetic form of a hormone produced naturally in the brain) at the same time or should have undergone bilateral orchidectomy (a surgical procedure to remove both testicles).

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## Efficacy

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The efficacy of Nubeqa, with the active substance darolutamide, was investigated in a study with 1,509 patients who had been diagnosed with non-metastatic castration-resistant prostate cancer and had a high risk of developing metastases.

In this study 955 patients were given the active substance darolutamide and 554 were given a

placebo (dummy drug). All patients in both groups were additionally given androgen suppression therapy (AST).

The patients treated with the active substance darolutamide survived for a median<sup>1</sup> of 40 months without their disease spreading, compared with 18 months in the placebo group.

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## Precautions, undesirable effects & risks

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Nubeqa must not be used if the patient has a hypersensitivity to the active substance darolutamide or any of the excipients in the tablet.

The most common side effect was tiredness, which was observed in 16% of the patients. Other side effects were pain in the arms and legs and skin rashes.

Patients treated with Nubeqa who are sexually active with a pregnant woman or a woman of

child-bearing age must use condoms during treatment and for 1 week after treatment has ended. Contact with androgen receptor inhibitors may damage the unborn child's development.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

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## Why the medicine has been authorised

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Prostate cancer is the second most common type of cancer in men, and the third most common type of cancer resulting in death in men in Europe. The disease is often fatal if left untreated.

Side effects such as tiredness, pain in the arms and legs and skin rashes were more common in the study participants who were treated

with Nubeqa. The side effects were mostly mild and treatable.

Based on the available data, and taking all the precautions into account, the benefits of Nubeqa outweigh the risks. Swissmedic has therefore authorised the medicine Nubeqa, with the active substance darolutamide, for use in Switzerland.

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## Further information on the medicinal product

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Information for patients (package leaflet):

[Information for patients Nubeqa®](#)

Information for healthcare professionals:

[Information for healthcare professionals Nubeqa®](#)

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

This information corresponds to that stated in the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.

<sup>1</sup>Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.