swissmedic

Summary report on authorisation dated 29 January 2026

Nubeqa® (active substance: darolutamide)

Indication extension in Switzerland: 28 July 2025

Film-coated tablets for the treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC)

About the medicinal product

The medicinal product Nubeqa contains the active substance darolutamide.

It is used in combination with androgen deprivation therapy (ADT)[1] for the treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC).

mHSPC is a type of prostate cancer that has spread to other areas of the body and that still responds to ADT for lowering the testosterone level.

Nubeqa was authorised by Swissmedic on 19 June 2020 for the treatment of adults with non-metastatic, castration-resistant prostate cancer in combination with ADT. On 17 January 2023, the indication extension for the treatment of adults with mHSPC in combination with docetaxel and ADT was authorised for the medicinal product Nubeqa. The current indication extension means that Nubeqa can now also be used in combination with ADT without docetaxel for the treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC).

The indication extension for Nubeqa was authorised in connection with "Project Orbis". Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. Currently, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Canada (HC), Israel (MOH), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are represented in Project Orbis.

[1] Androgen deprivation therapy (ADT): In ADT, the production of sex hormones, including testosterone, is reduced.

Mode of action

Darolutamide, the active substance in Nubeqa, is an androgen receptor inhibitor. This type of inhibitor prevents certain sex hormones, including testosterone, from binding 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.

Use

Nubeqa, containing the active substance darolutamide, is a prescription-only medicine.

The recommended dose is 600 mg (two 300 mg film-coated tablets) twice a day, which equates to a total dose of 1,200 mg per day. The film-coated tablets should be swallowed whole and taken at the same time as a meal.

The patients should also receive hormone-reducing therapy during the treatment with Nubeqa.

The treatment with Nubeqa should be continued until disease progression or unacceptable side effects occur.

Efficacy

The efficacy of Nubeqa was investigated in the ARANOTE study with 669 patients with mHSPC. The patients received either 600 mg Nubeqa or placebo (dummy drug) twice daily.

The primary efficacy endpoint[2] was radiographic progression-free survival[3].

The study showed that the treatment of patients with Nubeqa in combination with ADT resulted in a measurable improvement in progression-free survival compared to placebo and ADT.

Precautions, undesirable effects, & risks

Nubeqa must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common (affecting more than 1 in 10 users) undesirable effects are fatigue and altered blood values and liver parameters.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

[2] Primary efficacy endpoint: The primary endpoint is the main objective of the study determined before the trial starts. If the primary endpoint is reached or exceeded, the study proves that a treatment is effective.

[3] Radiographic progression-free survival: Time to disease progression assessed by imaging procedures or to death.

Why the medicinal product has been authorised

Prostate cancer is one of the most common types of cancer in men, and the stage of mHSPC is incurable.

The ARANOTE study showed a significant improvement in progression-free survival of patients treated with Nubeqa in combination with ADT compared to the control group. The difference in overall survival was not statistically significant at the time of the analysis.

Taking all the risks and precautions into account, and based on the available data, the benefits of Nubeqa outweigh the risks. Swissmedic has therefore authorised the medicinal product for the proposed indication of metastatic, hormone-sensitive prostate cancer.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Nubeqa®

Information for patients (package leaflet): Information for patients Nubeqa®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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.