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Nubeqa® (active substance: darolutamide)

Indication extension in Switzerland: 17 January 2023

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

About the medicine

The medicinal product Nubeqa contains the active substance darolutamide.

It is used in combination with docetaxel and 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 already authorised by Swissmedic, on 19 June 2020, for the treatment of adults with non-metastatic, castration-resistant prostate cancer in combination with ADT.

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), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic) and the United Kingdom (MHRA) are represented in Project Orbis.

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.

Docetaxel, which is administered in combination with darolutamide, is a

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

cytostatic agent that disrupts the growth of 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 medicine should be swallowed whole and taken at the same time as a meal.

Nubeqa is administered in combination with docetaxel. The first of a total of 6 docetaxel cycles should be administered within 6 weeks after the start of the Nubeqa treatment.

The treatment with Nubeqa should be continued until disease progression or unacceptable toxicity occurs.

Efficacy

The efficacy of Nubeqa in combination with docetaxel and ADT was investigated in the ARASENS study with 1,306 patients with mHSPC. The patients received either a twice daily dose of 600 mg Nubeqa or placebo (dummy drug) in the control arm, in each case in combination with 6 cycles of docetaxel and ADT.

The primary efficacy endpoint[2] was overall survival. The overall survival refers to the period between the start of treatment and the death of the patient. Another endpoint was the time to pain progression, which was assessed using a patient questionnaire.

Compared to the control arm, the treatment with Nubeqa in combination with docetaxel and ADT produced a statistically significant improvement in overall survival and a 32.5% reduction in the risk of mortality.

In patients treated with Nubeqa in combination with docetaxel and ADT, a statistically significant delay in the time to pain progression was observed (HR 0.79) compared to the control arm.

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 high blood pressure, skin rash, and elevated levels of bilirubin[3], alanine aminotransferase and aspartate aminotransferase[4] in blood tests.

All precautions, risks and other possible side 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. Secondary endpoints, on the other hand, refer to other effects that do not clearly prove efficacy or that do not allow any clear conclusions to be drawn about the actual target criterion (primary endpoint).

[3] Bilirubin: bilirubin forms as a result of the breakdown of the blood pigment haemoglobin, and an elevated bilirubin level in the blood may be a sign of liver damage.

[4] Aspartate aminotransferase and alanine aminotransferase: these are both enzymes produced mainly in the liver. Elevated blood levels of these enzymes in the blood may indicate liver-related diseases.

Why the medicinal product has been authorised

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.

The ARASENS study showed a significant improvement in overall survival of patients treated with Nubeqa in combination with docetaxel and ADT compared to the control arm.

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 in the Public Summary SwissPAR.

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