EMA/513180/2023
EMEA/H/C/004674

Talzenna (*talazoparib*)

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

What is Talzenna and what is it used for?

Talzenna is a cancer medicine used on its own to treat a type of breast cancer (HER2-negative with BRCA mutations) that has spread beyond the original site (locally advanced or metastatic), in patients who have been treated with certain medicines which have stopped working or when these medicines are not suitable.

Talzenna is also used together with another cancer medicine, enzalutamide, to treat adults who have castration-resistant prostate cancer that has spread to other parts of the body (metastatic) and who cannot have chemotherapy. Castration-resistant means that the disease has worsened despite treatment to lower testosterone levels, including surgical removal of the testes.

Talzenna contains the active substance talazoparib.

How is Talzenna used?

Talzenna can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the use of cancer medicines.

Talzenna is available as capsules to be taken by mouth once a day. The dose depends on the condition being treated. Treatment should continue for as long as the patient benefits from it and side effects are tolerable. The dose may be reduced or treatment interrupted if certain side effects develop.

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

How does Talzenna work?

The active substance in Talzenna, talazoparib, blocks the action of an enzyme called human poly-ADP ribose polymerase (PARP), which is a protein that helps to repair damaged DNA in cells (both normal and cancer cells) during cell division. When the PARP protein is blocked, the damaged DNA in cancer cells cannot be repaired, and as a result the cancer cells die.

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What benefits of Talzenna have been shown in studies?

Talzenna was shown to be effective at increasing the time patients live without their disease getting worse in two main studies.

The first main study involved 431 patients with HER2-negative breast cancer with BRCA mutations whose cancer had spread. Patients treated with Talzenna lived on average for 8.6 months without their disease getting worse compared with 5.6 months for patients treated with the doctor's choice of another cancer medicine.

A second main study involved 805 adults with castration-resistant prostate cancer that had spread to other parts of the body and who had not had chemotherapy. In this study, worsening of the disease could be seen on scans after around 22 months for people who received placebo (a dummy treatment). For those who received Talzenna, this time could not be calculated as not enough people had experienced worsening of their disease after about 28 months of follow up. In both groups, people also received enzalutamide.

What are the risks associated with Talzenna?

For the full list of side effects and restrictions with Talzenna, see the package leaflet.

The most common side effects with Talzenna (which may affect more than 1 in 5 people) are anaemia (low red blood cell counts), tiredness, nausea (feeling sick), neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), thrombocytopenia (low blood levels of platelets), and decreased appetite.

Women must not breastfeed during treatment with Talzenna and for a month after stopping treatment.

Why is Talzenna authorised in the EU?

Generally the outcome is poor for patients with HER2-negative breast cancer with BRCA mutations whose cancer has spread. Talzenna can increase the time these patients live without their disease getting worse. The medicine has also been found to be effective in the treatment of people with castration-resistant prostate cancer that has spread to other parts of the body and who cannot have chemotherapy. In these people, Talzenna can increase the time they live without their disease getting worse. The side effects with Talzenna were generally acceptable and when needed, manageable with dose modifications or standard supportive medical therapy.

The European Medicines Agency therefore decided that Talzenna’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 Talzenna?

The company that holds the marketing authorisation for Talzenna will provide the final results of the study looking at the effectiveness of the medicine together with enzalutamide in the treatment of adults with castration-resistant prostate cancer that has spread to other parts of the body and who cannot have chemotherapy.

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

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

Other information about Talzenna

Talzenna received a marketing authorisation valid throughout the EU on 20 June 2019.

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

This overview was last updated in 12-2023.