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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, in patients who have been treated with certain medicines which have stopped working or when these medicines are not suitable.

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 (1 mg and 0.25 mg) and the recommended dose is 1 mg once a day. Treatment should continue for as long as the patient continues to benefit 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 enzymes called human poly-ADP ribose polymerase (PARP), which are proteins that help to repair damaged DNA in cells (both in normal and in cancer cells) during cell division. Therefore, when PARP proteins are blocked, the damaged DNA in cancer cells cannot be repaired, and as a result the cancer cells die.

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 one main study involving 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.

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What are the risks associated with Talzenna?

The most common side effects with Talzenna (which may affect more than 1 in 4 people) are tiredness, anaemia (low red blood cell counts which can cause tiredness and pale skin), nausea (feeling sick), neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), thrombocytopenia (low blood levels of platelets), and headache. The most common severe side effects (which may affect more than 1 in 10 people) which led to changes in the dose of Talzenna are anaemia, neutropenia and thrombocytopenia.

Women must not breastfeed during treatment with Talzenna and for a month after stopping treatment. For the full list of side effects and restrictions with Talzenna, see the package leaflet.

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 side effects with Talzenna were generally well-tolerated and when needed, manageable with dose modifications, and/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?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Talzenna have 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

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