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Zejula (*niraparib*)

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

What is Zejula and what is it used for?

Zejula is a cancer medicine used in women with advanced ovarian cancer, which includes cancer of the ovaries, fallopian tubes (that connect the ovaries to the uterus) or the peritoneum (the lining around the abdomen). It can be used on its own for maintenance (continuing) treatment:

- In women newly diagnosed with advanced cancer in whom the cancer has shrunk or disappeared with a platinum-based medicines;
- in women whose cancer had relapsed (come back) after responding to previous treatment and in whom the cancer has shrunk or disappeared with a platinum-based medicine

Ovarian cancer is rare and Zejula was designated an 'orphan medicine' (a medicine used in rare diseases) on 4 August 2010. Further information on the orphan designation can be found here: ema.europa.eu/Find medicine/Human medicines/Rare disease designation

Zejula contains the active substance niraparib.

How is Zejula used?

Zejula is available as capsules (100 mg) to be taken by mouth. The dose is 2 or 3 capsules once a day, depending on the patient's weight, platelet count and whether or not the cancer has come back after previous treatment. Treatment should continue for as long as the patient benefits from it. The doctor may interrupt treatment or reduce the dose if the patient has certain side effects.

The medicine can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the use of cancer medicines.

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

How does Zejula work?

The active substance in Zejula, niraparib, blocks the action of enzymes called PARP-1 and PARP-2, which help to repair damaged DNA in cells when the cells divide to make new cells. By blocking PARP enzymes, the damaged DNA in cancer cells cannot be repaired, and, as a result, the cancer cells die.

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What benefits of Zejula have been shown in studies?

Zejula increased the time women lived without their disease getting worse in two main studies involving over 1,000 women with ovarian cancer, including fallopian tube or peritoneal cancers.

One study involved women with high-grade epithelial ovarian cancer that had come back after previous treatment with two or more platinum-based therapies. The women had a lasting response (the cancer had not progressed for at least 6 months) before the last platinum-based therapy. After treatment with Zejula, women lived on average 11.3 months without their disease getting worse compared with 4.7 months in women receiving placebo (a dummy treatment).

Another study involved women with advanced high-grade epithelial ovarian cancer that had only been treated with a platinum-based medicine and in whom the cancer had shrunk or disappeared. Women who then continued treatment with Zejula lived 13.8 months without their disease getting worse compared with 8.2 months in women receiving placebo (a dummy treatment).

What are the risks associated with Zejula?

The most common side effects with Zejula (which may affect more than 1 in 10 people) are nausea (feeling sick), thrombocytopenia (low blood platelet counts), tiredness and weakness, anaemia (low red blood cell counts), constipation, vomiting, abdominal (belly) pain, neutropenia (low levels of neutrophils, a type of white blood cell), insomnia (difficulty sleeping), headache, lack of appetite, diarrhoea, dyspnoea (difficulty breathing), hypertension (high blood pressure), back pain, dizziness, cough, joint pain, hot flushes and decrease in white blood cells. Serious side effects include thrombocytopenia and anaemia. For the full list of side effects of Zejula, see the package leaflet.

Zejula must not be used in women who are breastfeeding. For the full list of restrictions, see the package leaflet.

Why is Zejula authorised in the EU?

Although treatments for advanced ovarian cancer are available, the disease inevitably comes back. Zejula has been shown to prolong the time before the disease gets worse again in patients who have responded to platinum-based therapies. This may allow treatment for ovarian cancer to be delayed. Regarding safety, side effects are generally manageable with dose reductions.

The European Medicines Agency therefore decided that Zejula's benefits are greater than its risks and recommended that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Zejula?

The company that markets Zejula will submit the final analyses of the study on the effectiveness of Zejula in advanced epithelial (FIGO Stages III and IV) high-grade ovarian cancer.

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

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

Other information about Zejula

Zejula received a marketing authorisation valid throughout the EU on 16 November 2017.

Further information on Zejula can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/zejula.

This overview was last updated in 10-2020.