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EPAR summary for the public

Lynparza

olaparib

This is a summary of the European public assessment report (EPAR) for Lynparza. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Lynparza.

For practical information about using Lynparza, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lynparza and what is it used for?

Lynparza is a cancer medicine used for the 'maintenance' treatment of adult patients with high grade serous epithelial cancer of the ovary (a type of advanced cancer of the ovary), including cancer of the fallopian tubes (part of the female reproductive system that connect the ovaries to the uterus) and cancer of the peritoneum (the membrane lining the abdomen).

Lynparza is used in patients who have mutations (defects) in one of the two genes known as *BRCA1* and *BRCA2* and who have recurrent disease (when the cancer has come back after previous treatment). Lynparza is given after treatment with platinum-based medicines, when the tumour is diminishing in size or has completely disappeared. It is given to those patients whose previous treatment with platinum-based medicines led to a durable response (lasting 6 months or more).

Lynparza contains the active substance olaparib.

Because the number of patients with ovarian cancer is low, the disease is considered 'rare' and Lynparza was designated an 'orphan medicine' (a medicine used in rare diseases) on 6 December 2007.

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How is Lynparza used?

Lynparza is available as capsules (50 mg) to be taken by mouth. It can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the treatment of cancer.

Before starting treatment, patients must have confirmation that they have a *BRCA* mutation. This should be done by genetic testing in an appropriate laboratory.

Treatment with Lynparza is started no later than 8 weeks after finishing the last dose of the platinum-based chemotherapy. The recommended dose of Lynparza is 400 mg (eight capsules) taken twice a day. Treatment may be interrupted and doses may be reduced in patients who experience side effects. Lynparza should be taken at least one hour after food and patients should not eat preferably for up to two hours afterwards. For more information, see the package leaflet.

How does Lynparza work?

The active substance in Lynparza, olaparib, blocks the action of enzymes called human poly (ADP ribose) polymerase (PARP), which help to repair damaged DNA in cells (both in normal and in cancer cells) during cell division. In normal cells there is an alternative mechanism for repairing DNA which requires BRCA1 and BRCA2 proteins. This alternative mechanism does not work properly in cancer cells with mutations in the *BRCA1* or *BRCA2* genes. 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 Lynparza have been shown in studies?

Lynparza has been shown to increase the time patients live without their disease getting worse in one main study involving 265 patients. Patients in the study had high grade serous ovarian cancers, including fallopian tube or peritoneal. Patients had undergone treatment with two or more regimens of platinum-based chemotherapy, and they had had a durable response (the cancer had not progressed for at least 6 months) before the last regimen. This response to platinum medicines justified the use of the last platinum-based treatment. Lynparza was given not later than 8 weeks after the last cycle of platinum-based medicines, when the tumour was diminishing in size or had completely disappeared. Around half of the patients in the study had *BRCA* mutations. These mutations were, in most cases, hereditary.

Patients who had a *BRCA* mutation and were treated with Lynparza lived on average significantly longer without their disease getting worse than patients who had a *BRCA* mutation and were treated with placebo (a dummy treatment): 11.2 months versus 4.3 months, respectively.

What are the risks associated with Lynparza?

The most common side effects with Lynparza (which may affect more than 1 in 10 people) are fatigue (tiredness), nausea (feeling sick), vomiting, diarrhoea, dyspepsia (heartburn), headache, dysgeusia (taste disturbances), decreased appetite, dizziness, anaemia (low red blood cell counts), lymphopenia and neutropenia (low counts of certain types of white blood cell), mean corpuscular volume elevation (increase in the average size of red blood cells) and increase in creatinine (high levels of creatinine in blood indicates problems with kidney function). For the full list of all side effects reported for Lynparza, see the package leaflet.

Women must not breastfeed during treatment with Lynparza and for at least one month after treatment. For the full list of restrictions, see the package leaflet.

Why is Lynparza approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Lynparza's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that the benefit of Lynparza in prolonging survival of cancer patients with a *BRCA* mutation before their disease got worse was clinically relevant. These patients, who generally have poor prognosis, experienced an overall delay of 6.9 months in the progression of their disease, which might allow the next cycle of platinum-based chemotherapy to be delayed. Regarding safety, side effects were mostly mild or moderate and were generally manageable. The CHMP also noted that more studies are needed to further confirm the benefit of Lynparza, its effect on overall survival and its long-term safety.

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

A risk management plan has been developed to ensure that Lynparza is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Lynparza, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Lynparza will carry out studies to further confirm the benefit, including long-term benefit of the medicine in patients with ovarian cancer.

Further information can be found in the summary of the risk management plan.

Other information about Lynparza

The European Commission granted a marketing authorisation valid throughout the European Union for Lynparza on 16 December 2014.

The full EPAR and risk management plan summary for Lynparza can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Lynparza, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Lynparza can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 12-2014.