EMA/502202/2020
EMEA/H/C/003726

Lynparza (*olaparib*)

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

What is Lynparza and what is it used for?

Lynparza is a cancer medicine used for:

- continuing treatment after initial treatment of high-grade (fast-growing) cancers of the ovaries, fallopian tubes (which connect the ovaries to the womb), and the peritoneum (membrane lining the abdomen) in:
  - women whose cancer has come back (relapsed) after previous treatment and in whom platinum-based chemotherapy has shrunk or cleared the cancer;
  - women newly diagnosed with advanced cancer with mutations (changes) in one or both genes known as *BRCA1* and *BRCA2* who have been treated with platinum-based chemotherapy and in whom this treatment has shrunk or cleared the cancer;
  - women with advanced cancer that is HRD-positive (homologous recombination deficiency; where one of the mechanisms to repair damaged DNA does not work, which can be due to a defect in certain genes such as *BRCA1* and *BRCA2*) and in whom platinum-based chemotherapy and bevacizumab has shrunk or cleared the cancer;
- breast cancer which is HER2-negative and has spread beyond the original site in patients with mutations in *BRCA1* or *BRCA2* genes who have been treated with certain breast cancer medicines, and these medicines have stopped working or they were not suitable;
- continuing treatment of pancreatic cancer in patients with mutations in *BRCA1* or *BRCA2* genes, that is metastatic (has spread to other parts of the body) and has not worsened after at least 4 months of platinum-based chemotherapy;
- metastatic prostate cancer in men with mutations in *BRCA1* or *BRCA2* genes in whom medical or surgical treatment to lower testosterone levels (castration) did not work and whose cancer has worsened after treatment with other prostate cancer medicines, including a new hormonal agent.

Lynparza is either used alone or in combination with bevacizumab. It contains the active substance olaparib.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How is Lynparza used?

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

Lynparza is available as tablets (100 and 150 mg) and capsules (50 mg) which the patient takes twice a day. A lower dose is required for the tablets than for the capsules. While tablets can be taken with food or between meals, the patient should take the capsules at least 1 hour after food and not eat for up to 2 hours afterwards.

The dose and the choice between capsules and tablets of Lynparza depends on what disease it is being used for. Treatment is continued for as long as the patient benefits from it. In advanced ovarian cancer, the doctor may stop treatment after 2 years if X-rays show no signs of the cancer. Treatment may be interrupted or stopped, or the dose reduced if certain side effects develop.

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

How does Lynparza work?

The active substance in Lynparza, olaparib, blocks the action of an enzyme called human poly ADP ribose polymerase (PARP), which helps to repair damaged DNA in cells (both in normal and cancer cells) during cell division. Cancer cells with mutations such as the *BRCA1* or *BRCA2* mutations rely more heavily on PARP to repair their DNA and continue dividing. Therefore, when PARP is 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?

Ovarian cancer

Studies show that Lynparza given on its own increases the time women with cancer of the ovary, fallopian tube or peritoneum live without their disease getting worse after treatment with platinum-based chemotherapy has shrunk or cleared the cancer:

- A study involving 295 patients with relapsed cancer found that those receiving Lynparza lived on average for 19.1 months without their disease getting worse compared with 5.5 months for patients receiving placebo (a dummy treatment).
- In another study involving 265 patients with relapsed cancer, those who took Lynparza lived on average for 8.4 months without their disease getting worse compared with 4.8 months for patients on placebo.
- In a third study involving 391 patients with advanced cancer who had *BRCA1* or *BRCA2* mutations, the disease did not get worse in around 74% of patients who took Lynparza for 2 years compared with 35% of patients on placebo.

When given with bevacizumab, Lynparza increases the time patients with HRD-positive cancer live without their disease getting worse after treatment with platinum-based chemotherapy and bevacizumab has shrunk or cleared the cancer. In a main study of 806 patients with advanced high-grade ovarian, fallopian tube or peritoneal cancer, patients whose cancer was HRD-positive and who took Lynparza for 22 months lived on average 37.2 months without their disease getting worse compared with 17.7 months for those receiving placebo.

Breast cancer

Lynparza was effective in a study involving 302 patients with HER2-negative breast cancer with *BRCA1* or *BRCA2* mutations whose cancer had spread. Patients treated with Lynparza lived on average 7.0 months without their disease getting worse compared with 4.2 months for patients treated with the doctor's choice of another cancer medicine.

Pancreatic cancer

In a study of 154 patients with *BRCA1* or *BRCA2* mutations who had metastatic pancreatic cancer that had not got worse during at least 4 months of treatment with platinum-based chemotherapy, Lynparza increased the time patients lived without their disease getting worse: those receiving Lynparza lived on average 7.4 months without their disease getting worse compared with 3.8 months for patients receiving placebo.

Prostate cancer

In a study of 387 men with metastatic castration-resistant prostate cancer whose cancer had worsened during treatment with another cancer medicine, Lynparza was effective in patients with mutations in *BRCA1* or *BRCA2* genes (160 patients overall): Patients with these mutations and treated with Lynparza lived on average 9.8 months without their disease getting worse, compared with 3.0 months in those treated with the doctor's choice of another cancer medicine.

What are the risks associated with Lynparza?

The most common side effects with Lynparza (which may affect more than 1 in 10 people) are tiredness, nausea (feeling sick), vomiting, diarrhoea, dyspepsia (heartburn), cough, headache, dysgeusia (taste disturbances), decreased appetite, dizziness, dyspnoea (difficulty breathing), anaemia (low red blood cell counts), leucopenia (low white blood cell counts), neutropenia (low levels of neutrophils, a type of white blood cell that fights infection) and thrombocytopenia (low blood platelet counts).

The most common severe side effects (which may affect more than 2 in 100 people) are low blood cell counts, tiredness, weakness and vomiting.

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

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

Why is Lynparza authorised in the EU?

Generally, the outcome is poor for patients with ovarian, fallopian tube, or peritoneal cancers and for patients with HER2-negative breast cancer, pancreatic cancer with *BRCA* mutations or prostate cancer with *BRCA* mutations whose cancer has spread. Lynparza can increase the time these patients live without their disease getting worse. In ovarian, fallopian tube or peritoneal cancers, Lynparza can also delay the need for the next cycle of platinum chemotherapy.

The side effects with Lynparza are mostly mild or moderate and are generally manageable. The European Medicines Agency therefore decided that Lynparza'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 Lynparza?

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.

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

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

Other information about Lynparza

Lynparza received a marketing authorisation valid throughout the EU on 16 December 2014.

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

This overview was last updated in 11-2020.