



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 on its own for:

- continuing 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 had come back (relapsed) after previous treatment and in whom platinum-based chemotherapy has reduced or cleared the cancer;
 - in newly diagnosed women 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 reduced or cleared the cancer;
- treatment of breast cancer which is HER2-negative and that has spread beyond the original site in patients with mutations in *BRCA1* or *BRCA2* genes who have been treated with certain breast cancer medicines (unless these medicines were not suitable).

Lynparza contains the active substance olaparib.

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. The doses in milligrams are different for the tablets and capsules. Furthermore, 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 disease is not getting worse. 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.

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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. 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?

Ovarian cancer

Studies show that Lynparza increases the time patients live without their disease getting worse after treatment with platinum-based chemotherapy has reduced or cleared the cancer:

- A study of 295 patients with relapsed cancer of the ovary, fallopian tube or peritoneum 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 *BRCA1/2* mutations, the disease had not got worse in around 74% of patients who took Lynparza for 2 years compared with 35% of patients on placebo.

Breast cancer

Lynparza was effective in a study involving 302 patients with HER2-negative breast cancer with *BRCA1/2* 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.

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, upper abdominal pain (stomach ache), 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).

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 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 next cycle of platinum chemotherapy.

The side effects with Lynparza were mostly mild or moderate and were 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 06-2019.