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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 for treating recurring high-grade cancers of the ovary, fallopian tube (tubes connecting the ovary to the womb) and the peritoneum (a membrane lining the abdomen).

Lynparza is used as a maintenance treatment after the cancer has been reduced or cleared by a platinum-based chemotherapy.

It contains the active substance olaparib.

How is Lynparza used?

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 the capsules must be taken without food while tablets can be taken with or without food.

Treatment should start no later than 8 weeks after the patient has completed their chemotherapy and continue for as long as the disease is not getting worse.

The medicine can only be obtained with a prescription. 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 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?

Studies show that Lynparza increases the time patients can live without their disease getting worse after initial treatment with a platinum chemotherapy has reduced or cleared the tumours.

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A study of 295 patients with recurring cancer of the ovary, fallopian tube or peritoneum showed that those patients who took Lynparza lived on average for 19.1 months without their disease getting worse compared with 5.5 months for patients who took placebo (a dummy treatment).

In another study involving 265 patients, 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.

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

Why is Lynparza authorised in the EU?

Patients with ovarian, fallopian tube or peritoneal cancers generally have a poor outcome. Lynparza can increase the time these patients live without their disease getting worse, thereby delaying their next cycle of platinum chemotherapy.

The side effects seen 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/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 04-2018.