

Package leaflet: Information for the patient

Lynparza® 150 mg film-coated tablets

(olaparib)

The name of your medicine is Lynparza 150 mg film-coated tablets but will be referred to as Lynparza throughout this leaflet.

Please note that the leaflet also contains information about another strength.

APPROVED
By Lily Collier at

1000149903-xxx-xx

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lynparza is and what it is used for
2. What you need to know before you take Lynparza
3. How to take Lynparza
 - A test is used to find out whether you have *BRCA*-mutated ovarian cancer.
4. Possible side effects
5. How to store Lynparza
6. Contents of the pack and other information

1. What Lynparza is and what it is used for

What Lynparza is and how it works

Lynparza contains the active substance olaparib. Olaparib is a type of cancer medicine called a PARP inhibitor (poly [adenosine diphosphate-ribose] polymerase inhibitor).

PARP inhibitors can destroy cancer cells that are not good at repairing DNA damage. These specific cancer cells can be identified by:

- response to platinum chemotherapy, or
- looking for faulty DNA repair genes, such as *BRCA* (BReast CAncer) genes.

When Lynparza is used in combination with abiraterone (an androgen receptor signalling inhibitor), the combination may help enhance anti-cancer effect in prostate cancer cells with or without faulty DNA repair genes (e.g., *BRCA* genes).

What Lynparza is used for

Lynparza is used for the treatment of

- **a type of ovarian cancer (*BRCA*-mutated) that has responded to the first treatment with standard platinum-based chemotherapy.**
 - A test is used to find out whether you have *BRCA*-mutated ovarian cancer.
- **ovarian cancer that has come back (recurred).** It can be used after the cancer has responded to previous treatment with standard platinum-based chemotherapy.
- **a type of ovarian cancer (HRD positive as defined by a *BRCA* mutation or genomic instability) that has responded to the first treatment with standard platinum-based chemotherapy and bevacizumab.** Lynparza is used together with bevacizumab.
- **a type of breast cancer (*BRCA*-mutated, *HER2*-negative) when the cancer has not spread to other parts of the body and treatment is going to be given after surgery (treatment after surgery is called adjuvant therapy). You should have received chemotherapy medicines before or after surgery. If your cancer is hormone-receptor positive your doctor may also prescribe hormonal treatment.**
 - A test is used to find out whether you have *BRCA*-mutated breast cancer.
- **a type of breast cancer (*BRCA*-mutated, *HER2*-negative) which has spread beyond the original tumour.** You should have received chemotherapy medicines either before or after your cancer has spread.
 - A test is used to find out whether you have *BRCA*-mutated breast cancer.
- **a type of pancreatic cancer (*BRCA*-mutated) that has responded to the first treatment with standard platinum-based chemotherapy.**
 - A test is used to find out whether you have *BRCA*-mutated pancreatic cancer.
- **a type of prostate cancer (*BRCA*-mutated) which has spread beyond the original tumour and no longer responds to medical or surgical treatment to lower testosterone.** You should have received certain hormonal treatments, such as enzalutamide or abiraterone acetate.
 - A test is used to find out whether you have *BRCA*-mutated prostate cancer.
- **a type of prostate cancer that has spread to other parts of the body (metastatic) beyond the original tumour and no longer responds to a medical or surgical treatment that lowers testosterone.** Lynparza is used in combination with another anti-cancer medicine called abiraterone, together with the steroid medicine, prednisone or prednisolone.
- **a type of uterine cancer (MMR-proficient endometrial cancer) that has spread beyond the original tumour or come back (recurred).** Lynparza is used together with durvalumab if the cancer has not progressed after initial treatment with chemotherapy (carboplatin and paclitaxel) in combination with durvalumab.
 - A test is used to find out whether you have MMR-proficient endometrial cancer.

When Lynparza is given in combination with other anti-cancer medicines it is important that you also read the package leaflets of these other medicines. If you have any questions about these medicines, ask your doctor.

2. What you need to know before you take Lynparza

Do not take Lynparza

- if you are allergic to olaparib or any of the other ingredients of this medicine (listed in section 6)
- if you are breast-feeding (see section 2 below for more information).

Do not take Lynparza if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before taking Lynparza.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before or during treatment with Lynparza

- if you have low blood cell counts on testing. These may be low counts for red or white blood cells, or low platelet counts. See section 4 for more information about these side effects, including the signs and symptoms you need to look out for (for example, fever or infection, bruising or bleeding). Rarely, these may be a sign of more serious problems with the bone marrow such as 'myelodysplastic syndrome' (MDS) or 'acute myeloid leukaemia' (AML). When Lynparza is used in combination with another anti-cancer medicine (durvalumab), a low blood cell count could be a sign of 'pure red cell aplasia' (PRCA), a condition in which no red blood cells are produced, or 'auto-immune haemolytic anaemia' (AIHA), an excessive breakdown of red blood cells.
- if you experience any new or worsening symptoms of shortness of breath, coughing or wheezing. A small number of patients treated with Lynparza reported inflammation of the lungs (pneumonitis). Pneumonitis is a serious condition that can often require hospital treatment.
- if you experience any new or worsening symptoms of pain or swelling in an extremity, shortness of breath, chest pain, breathing that is more rapid than normal or heart beats faster than normal. A small number of patients treated with Lynparza were reported to develop a blood clot in a deep vein, usually in the leg (venous thrombosis), or a clot in the lungs (pulmonary embolism).
- if you notice yellowing of your skin or the whites of your eyes, abnormally dark urine (brown coloured), pain on the right side of your stomach area (abdomen), tiredness, feeling less hungry than usual or unexplained nausea and vomiting contact your doctor immediately as this may indicate problems with your liver.

If you think any of these may apply to you, talk to your doctor, pharmacist or nurse before or during treatment with Lynparza.

Tests and checks

Your doctor will check your blood before and during treatment with Lynparza.

You will have a blood test

- before treatment
- every month for the first year of treatment
- at regular intervals decided by your doctor after the first year of treatment.

If your blood count falls to a low level, you may need to have a blood transfusion (where you are given new blood or blood-based products from a donor).

Other medicines and Lynparza

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Lynparza can affect the way some other medicines work. Also, some other medicines can affect the way Lynparza works.

Tell your doctor, pharmacist or nurse if you are taking or are planning to take any of the following medicines

- any other anticancer medicines
- a vaccine or a medicine that suppresses the immune system, as you may need to be closely monitored
- itraconazole, fluconazole - used for fungal infections
- telithromycin, clarithromycin, erythromycin - used for bacterial infections
- protease inhibitors boosted with ritonavir or cobicistat, boceprevir, telaprevir, nevirapine, efavirenz - used for viral infections, including HIV
- rifampicin, rifapentine, rifabutin - used for bacterial infections, including tuberculosis (TB)
- phenytoin, carbamazepine, phenobarbital - used as a sedative or to treat fits (seizures) and epilepsy
- herbal remedies containing St John's Wort (*Hypericum perforatum*) - used mainly for depression
- digoxin, diltiazem, furosemide, verapamil, valsartan - used to treat heart conditions or high blood pressure
- bosentan - used to treat pulmonary artery hypertension
- statins, for example simvastatin, pravastatin, rosuvastatin - used to lower blood cholesterol levels
- dabigatran - used to thin the blood
- glibenclamide, metformin, repaglinide - used to treat diabetes
- ergot alkaloids - used to treat migraines and headaches
- fentanyl - used to treat cancer pain
- pimozone, quetiapine - used to treat mental health problems
- cisapride - used to treat stomach problems
- colchicine - used to treat gout
- cyclosporine, sirolimus, tacrolimus - used to suppress the immune system
- methotrexate - used to treat cancer, rheumatoid arthritis and psoriasis.

Tell your doctor, pharmacist or nurse if you are taking any of the above or any other medicines. The medicines listed here may not be the only ones that could affect Lynparza.

Lynparza with drink

Do not drink grapefruit juice while you are being treated with Lynparza. It can affect the way the medicine works.

Contraception, pregnancy and breast-feeding

Female patients

- You should not take Lynparza if you are pregnant or might become pregnant. This is because it may harm an unborn baby.
- You should not become pregnant while taking this medicine. If you are having sex, you should use two effective methods of contraception while taking this medicine and for 6 months after taking the last dose of Lynparza. It is not known whether Lynparza may affect the effectiveness of some hormonal contraceptives. Please tell your doctor if you are taking a hormonal contraceptive, as your doctor may recommend the addition of a non-hormonal contraceptive method.
- You should have a pregnancy test before starting Lynparza, at regular times during treatment and 6 months after taking the last dose of Lynparza. If you become pregnant during this time, you must talk to your doctor straight away.
- It is not known whether Lynparza passes into breast milk. Do not breast-feed if you are taking Lynparza and for 1 month after taking the last dose of Lynparza. If you are planning to breast-feed, tell your doctor.

Male patients

- You must use a condom when having sex with a female partner, even if she is pregnant, while taking Lynparza and for 3 months after taking the last dose. It is not known whether Lynparza passes into semen.
- Your female partner must also use a suitable method of contraception.
- You must not donate sperm while taking Lynparza and for 3 months after taking the last dose.

Driving and using machines

Lynparza may influence your ability to drive and use machines. If you feel dizzy, weak or tired while taking Lynparza, do not drive or use tools or machines.

Information on other ingredients in this medicine

This medicine contains less than 1 mmol sodium (23 mg) per 100 mg or 150 mg tablet, that is to say essentially "sodium-free".

3. How to take Lynparza

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

How to take

- Swallow Lynparza tablets whole, with or without food.
- Take Lynparza once in the morning and once in the evening.
- Do not chew, crush, dissolve or divide the tablets as this may affect how quickly the medicine gets into your body.

How much to take

- Your doctor will tell you how many tablets of Lynparza to take. It is important that you take the total recommended dose each day. Keep doing so for as long as your doctor, pharmacist or nurse tells you to.
- The usual recommended dose is 300 mg (2 x 150 mg tablets) twice a day - a total of 4 tablets each day.

Your doctor may prescribe a different dose if

- you have problems with your kidneys. You will be asked to take 200 mg (2 x 100 mg tablets) twice a day - a total of 4 tablets each day.
- you are taking certain medicines that may affect Lynparza (see section 2).
- you have certain side effects while you are taking Lynparza (see section 4). Your doctor may lower your dose or stop treatment, either for a short time or permanently.

If you take more Lynparza than you should

If you take more Lynparza than your normal dose, contact your doctor or the nearest hospital straight away.

If you forget to take Lynparza

If you forget to take Lynparza, take your next normal dose at its scheduled time. Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor straight away if you notice any of the following

Side effects reported in clinical studies with patients receiving Lynparza alone:

Very common (may affect more than 1 in 10 people)

- feeling short of breath, feeling very tired, pale skin or fast heart beat – these may be symptoms of a decrease in the number of red blood cells (anaemia).

Uncommon (may affect up to 1 in 100 people)

- allergic reactions (e.g. hives, difficulty breathing or swallowing, dizziness which are signs and symptoms of hypersensitivity reactions).
- itchy rash or swollen, reddened skin (dermatitis).
- serious problems with bone marrow (myelodysplastic syndrome or acute myeloid leukaemia). See section 2.

Other side effects include

Very common (may affect more than 1 in 10 people)

- feeling sick (nausea)
- being sick (vomiting)
- feeling tired or weak (fatigue)
- indigestion or heartburn (dyspepsia)
- loss of appetite
- headache
- changes in taste of foods (dysgeusia)
- feeling dizzy
- cough
- shortness of breath (dyspnoea)
- diarrhoea - if it gets severe, tell your doctor straight away.

Very common side effects that may show up in blood tests

- low white blood cell count (leukopenia or neutropenia) which may decrease your ability to fight infection and may be associated with fever.

Common (may affect up to 1 in 10 people)

- rash
- sore mouth (stomatitis)
- pain in the stomach area under the ribs (upper abdominal pain).
- blood clot in a deep vein, usually in the leg (venous thrombosis) that may cause symptoms such as pain or swelling of the legs, or a clot in the lungs (pulmonary embolism) that may cause symptoms such as shortness of breath, chest pain, breathing that is more rapid than normal or heart beats faster than normal.

Common side effects that may show up in blood tests

- low white blood cell count (lymphopenia) which may decrease your ability to fight infection and may be associated with fever
- decrease in the number of platelets in blood (thrombocytopenia) - you may notice the following symptoms
 - bruising or bleeding for longer than usual if you hurt yourself
- increase in blood creatinine - this test is used to check how your kidneys are working.
- abnormal liver function tests.

Uncommon side effects that may show up in blood tests

- increase in the size of red blood cells (not associated with any symptoms).

Rare (may affect up to 1 in 1,000 people)

- facial swelling (angioedema).
- painful inflammation of the fatty tissue under the skin (erythema nodosum).

Not known (cannot be estimated from available data)

- signs of liver problems, such as yellowing of your skin or the whites of your eyes (jaundice), nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (brown coloured), feeling less hungry than usual, tiredness.

Side effects reported in a clinical study with patients receiving Lynparza with durvalumab after initial treatment with chemotherapy (carboplatin and paclitaxel) with durvalumab, that occurred at a higher frequency than in patients receiving Lynparza alone:

Very common (may affect more than 1 in 10 people)

- decrease in the number of platelets in blood (thrombocytopenia) - you may notice the following symptoms
 - bruising or bleeding for longer than usual if you hurt yourself
- rash

Common (may affect up to 1 in 10 patients) side effects when using Lynparza with durvalumab

- allergic reactions (e.g. hives, difficulty breathing or swallowing, dizziness which are signs and symptoms of hypersensitivity reactions).

In addition, the following side effect was reported in patients receiving Lynparza with durvalumab:

Common (may affect up to 1 in 10 patients):

- failure to produce red blood cells (pure red cell aplasia) which can be associated with symptoms of shortness of breath, fatigue, pale skin or fast heart beat.

Your doctor will test your blood every month for the first year of treatment and at regular intervals after that. Your doctor will tell you if there are any changes in your blood test that might need treatment.

If you notice any side effects not listed in this leaflet, please contact your doctor straight away.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lynparza

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original package in order to protect from moisture.

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lynparza contains

The active substance is olaparib.

- Each film-coated tablet contains 150 mg olaparib.

The other ingredients (excipients) are

- Tablet core: copovidone, colloidal silica dioxide, mannitol, sodium stearyl fumarate
- Tablet coating: hypromellose, macrogol 400, titanium dioxide (E171), iron oxide yellow (E172), iron oxide black (E172).

See section 2 "Information on other ingredients in this medicine".

What Lynparza looks like and contents of the pack

Lynparza 150 mg tablets are green to green/grey, oval, bi-convex, film-coated tablets, marked with "OP150" on one side and plain on the other.

Lynparza is supplied in packs containing 56 film-coated tablets (7 blisters of 8 tablets each).

Product Licence Holder and Manufacturer

Procured from within the EU by the Product Licence holder Orifarm UK Ltd., Ground Floor Suite A2, Breakspear Park, Breakspear Way, Hemel Hempstead, HP2 4TZ, UK

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Lynparza 150 mg film-coated tablets

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