

Package leaflet: Information for the patient

Lynparza 50 mg hard capsules olaparib

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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
4. Possible side effects
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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).

In patients with mutations (changes) in certain genes called *BRCA* (breast cancer gene), who are at risk of developing some forms of cancer, PARP inhibitors are able to trigger the death of cancer cells by blocking an enzyme that helps repair DNA.

What Lynparza is used for

Lynparza is used for the treatment of a type of ovarian cancer called “*BRCA*-mutated ovarian cancer”. It is used after the cancer has responded to previous treatment with standard platinum-based chemotherapy. A test is used to determine whether you have *BRCA*-mutated cancer.

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).
- 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 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
- pimozide, 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

- 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. You should use effective methods of contraception while taking this medicine and for 1 month 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 1 month 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.

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.

3. How to take Lynparza

Your doctor has prescribed Lynparza **capsules** for you. Please note Lynparza is also available as a 100 mg and 150 mg **tablet**.

- The doses of Lynparza capsules and tablets are not the same.

Taking the wrong dose or a tablet instead of a capsule could lead to Lynparza not working properly or to more side effects.

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

- Take one dose (8 capsules) of Lynparza by mouth with water, once in the morning and once in the evening.
- Take Lynparza at least one hour after eating food. Do not eat preferably for up to 2 hours after taking Lynparza.

How much to take

- Your doctor will tell you how many capsules 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 8 capsules (400 mg) taken by mouth twice a day (a total of 16 capsules each day).

Your doctor may prescribe a different dose if:

- you have problems with your kidneys. You will be asked to take 6 capsules (300 mg) twice a day - a total of 12 capsules 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 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:

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).

Other side effects include:

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

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

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

- rash or itchy rash on swollen, reddened skin (dermatitis)
 - sore mouth (stomatitis).
 - pain in the stomach area under the ribs (upper abdominal pain).

Common side effects that may show up in blood tests:

- 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
- low white blood cell count (leukopenia, neutropenia or lymphopenia) which may decrease your ability to fight infection and may be associated with fever
- increase in blood creatinine - this test is used to check how your kidneys are working.

Uncommon side effects that may show up in blood tests:

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

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

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 bottle after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Do not freeze. Throw away any Lynparza capsules that have been frozen.

If preferred, you can keep Lynparza capsules out of the refrigerator (below 30°C) for up to 3 months.

After this period, throw away any capsules that have not been used. It is recommended that you record

the date when the capsules are removed from refrigerator and the date after which they should be discarded.

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 hard capsule contains 50 mg of olaparib.

The other ingredients (excipients) are:

- Capsule content: lauroyl macrogol-32 glycerides.
- Capsule shell: hypromellose, titanium dioxide (E171), gellan gum (E418), potassium acetate.
- Printing ink: shellac, iron oxide black (E172).

What Lynparza looks like and contents of the pack

Lynparza is a white, opaque, hard capsule, marked with “OLAPARIB 50 mg” and the AstraZeneca logo in black ink.

Lynparza is provided in HDPE plastic bottles containing 112 hard capsules. One pack contains 448 capsules (4 bottles of 112 capsules).

Marketing Authorisation Holder

AstraZeneca AB
SE-151 85 Södertälje
Sweden

Manufacturer

AstraZeneca UK Limited
Silk Road Business Park
Macclesfield, Cheshire, SK10 2NA
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

AstraZeneca UK Ltd
Tel: +44 1582 836 836

Ireland

AstraZeneca Pharmaceuticals (Ireland) DAC
Tel: +353 1609 7100

Malta

Associated Drug Co. Ltd
Tel: +356 2277 8000

This leaflet was last revised in July 2018.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.

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