

Lynparza[®] Capsules

Olaparib 50 mg Capsule.

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Lynparza**. It does not contain all the information that is known about **Lynparza capsules**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Lynparza capsules** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Lynparza is used for

You will have been prescribed **Lynparza capsules** if you have ovarian cancer and it has responded to treatment with platinum-based chemotherapy and you have a mutation of the BRCA gene. BRCA stands for "BRCA Cancer" gene. A genetic test will be done to determine if you have the BRCA gene mutation.

Lynparza is a PARP (Poly (ADP-Ribose) Polymerase enzymes) inhibitor. It works by destroying cancer cells when both copies of the BRCA gene, are faulty (mutated). Carriers of a mutated BRCA gene have a higher risk of developing certain cancers, including ovarian cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you use Lynparza

When you must not use it

Do not take **Lynparza capsules** if you have an allergy to:

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are pregnant or intend to become pregnant. It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine. It is not known if the active ingredient in **Lynparza capsules** passes into breast milk. Breast-feeding mothers are advised not to breast-feed during treatment with **Lynparza capsules** and for one month after receiving the last dose.

Do not give this medicine to children. Safety and effectiveness in children younger than 18 years has not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- problems with your kidneys or liver (renal or hepatic impairment)
- problems with your blood (e.g. anaemia, low white blood cell counts, low red blood cell counts or low platelet counts).

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking **Lynparza capsules**.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

You should not take **Lynparza** if you are taking any other anti-cancer agents.

Some medicines or foods and **Lynparza** may interfere with each other and reduce effectiveness. These include:

- medicines used to treat fungal infections (antifungals) with active ingredients such as fluconazole, ketoconazole, itraconazole
- medicines used to treat bacterial infections (antibiotics) with active ingredients such as clarithromycin, rifampicin, rifabutin, ciprofloxacin, erythromycin
- medicines used to treat viral infections (especially HIV) with active ingredients such as ritonavir, indinavir, saquinavir, nevirapine, boceprevir, cobicistat, etravine and efavirenz
- medicines used to treat epilepsy with active ingredients such as phenytoin, carbamazepine and phenobarbital
- medicines with active ingredients such as modafinil used to treat a sleep disorder called narcolepsy (where you may experience very sleepy periods at odd times during the day)
- medicines to treat high blood pressure, angina (chest pain), irregular heartbeat or heart failure such as diltiazem, furosemide, valsartan and verapamil
- bosentan, a medicine to treat pulmonary artery hypertension
- medicines called statins used to treat high cholesterol such as rosuvastatin and atorvastatin
- medicines used to suppress the immune system such as tacrolimus, cyclosporin and sirolimus
- methotrexate, a medicine used to treat cancer, rheumatoid arthritis and psoriasis
- fentanyl, a medicine used to manage pain
- quetiapine, a medicine used to treat mental disorders
- colchicine, a medicine used to treat gout
- dabigatran, a medicine to prevent blood clots
- grapefruit, Seville oranges and star fruit
- St John's Wort, used to treat depression
- medicines used to treat diabetes such as metformin and glibenclamide
- cisplatin, a medicine used to treat cancer
- ergot alkaloids, medicines used to treat migraines and headaches
- cisapride, a medicine used to treat stomach problems.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of these things, tell them before you take any **Lynparza**.

How to take Lynparza capsules

Your doctor has prescribed Lynparza Capsules for you. Please note **Lynparza** is also available as 100 mg and 150 mg tablets. 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.

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. **If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.**

How much to take

The usual dose is eight capsules taken twice each day (a total of 16 capsules each day). You should not take any more or any less capsules unless your doctor tells you to.

Your doctor may prescribe a different dose if you have problems with your kidneys, or are taking certain medicines that may interact with **Lynparza capsules** or if you experience certain side effects while you are taking **Lynparza capsules**.

Your doctor will tell you how many capsules of **Lynparza** to take and it is important that you take the total recommended daily dose.

How to take it

Swallow the capsules whole with a glass of water. Do not open the capsules.

When to take it

Take Lynparza capsules about the same time each morning and evening. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take your medicine on an empty stomach at least 1 hour after food. Once **Lynparza** is taken, do not eat for 2 hours. Food can interfere with the absorption of this medicine.

How long to take it

Continue taking your medicine for as long as your doctor tells you. It is important to keep taking your medicine even if you feel well. Continue taking your medicine until you finish the pack.

If you forget to take it

If you forget to take **Lynparza capsules**, 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 forgotten capsules.

If you are not sure what to do, ask your doctor. If you have trouble remembering to take your medicine, ask your doctor or pharmacist for some hints.

If you take too much (overdose)

Please telephone your doctor or the National Poisons Information Centre on 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much **Lynparza**, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Lynparza

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Lynparza. Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately. You should not become pregnant while taking **Lynparza**. If you are at risk of becoming pregnant you must use effective contraception during treatment and for 1 month after receiving the last dose of **Lynparza**.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects. Your doctor will test your blood every month for the first year of treatment and periodically thereafter.

Things you must not do

Do not take **Lynparza capsules** to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen.

Your doctor may interrupt your treatment or reduce your dose if you are having unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how **Lynparza** affects you.

This medicine may cause dizziness and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lynparza capsules. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately if you notice any of the following:

- feeling or being sick (nausea or vomiting)
- dizziness, tiredness or weakness
- indigestion or heartburn
- loss of appetite
- headache
- change in taste of food (if it worries you)
- diarrhoea
- sore mouth
- cough
- shortness of breath
- pain in the stomach area under the ribs

- shortness of breath and/or a dry cough which can be due to inflammation of the lungs (pneumonitis).
- rash, itchy swollen reddened skin
- facial swelling

The above list includes serious side effects that may require medical attention and can be life-threatening, especially if not treated.

If any of the following happen, tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- tightness of the chest, wheezing, coughing, shortness of breath or difficulty breathing.
- swelling of the face, lips, tongue or other parts of the body.
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to **Lynparza**. You may need urgent medical attention or hospitalisation.

Some other serious side effects may only become known through tests. Your doctor will test your blood every month for the first year of treatment and periodically thereafter.

The blood tests may show:

- a condition where there is damage to the blood-forming cells in your bone marrow (myelodysplastic syndrome/acute myeloid leukaemia)
- decrease in the number of red blood cells (anaemia) which can be associated with shortness of breath, fatigue, pale skin, or fast heart beat
- decrease in white blood cells (neutropenia, leukopenia and lymphopenia), which can be associated with increased susceptibility to infection and/or symptoms of fever
- increase in blood creatinine which can mean your kidneys are not working as well
- decrease in the number of platelets (thrombocytopenia), which can result in bruising or bleeding for longer than normal if injured.
- increase in the size of red blood cells (not associated with any symptoms).

Tell your doctor if you notice any of the symptoms above that may be because of changes in your blood. These conditions may also be life-threatening, especially if not treated. Your doctor will tell you if your test results are abnormal and if you need treatment to correct for these side effects in your blood.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

How to store Lynparza Capsules

Storage

Keep your capsules in the bottle until it is time to take them. If you take the capsules out of the bottle they may not keep well.

Keep your capsules in a refrigerator where the temperature stays between 2°C and 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 in a cool, dry place where the temperature stays below 30°C for up to 3 months. After this period, throw away any capsules that have not been used.

Do not store **Lynparza** or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What Lynparza capsules look like and contents of the pack

Lynparza 50 mg capsules are white and are marked with “OLAPARIB 50 mg” and the AstraZeneca logo printed in black ink.

Lynparza is available in cartons containing 4 plastic bottles. Each bottle contains 112 capsules.

Ingredients

Lynparza capsules contains 50 mg of olaparib as the active ingredient and the following inactive ingredients:

- lauroyl macrogol-32 glycerides, hypromellose, gellan gum, titanium dioxide, potassium acetate, shellac and iron oxide black

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes. The capsule shell is made of hypromellose and does not contain gelatin.

Marketed by

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