

LYNPARZA® Tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using LYNPARZA tablets?

LYNPARZA tablets contain the active ingredient olaparib. LYNPARZA tablets are used to treat certain types of ovarian cancer, breast cancer, pancreatic cancer and prostate cancer.

For more information, see Section [1. Why am I using LYNPARZA tablets?](#) in the full CMI.

2. What should I know before I use LYNPARZA tablets?

Do not use if you have ever had an allergic reaction to LYNPARZA tablets or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use LYNPARZA tablets?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LYNPARZA tablets and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use LYNPARZA tablets?

- The usual dose is two 150 mg tablets taken twice each day (a total of 4 tablets each day). Your doctor may prescribe a different dose.
- Follow the instructions provided and use LYNPARZA tablets until your doctor tells you to stop.

More instructions can be found in Section [4. How do I use LYNPARZA tablets?](#) in the full CMI.

5. What should I know while using LYNPARZA tablets?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, surgeon, anesthetist, dentist or pharmacist you visit that you are using LYNPARZA tablets.
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	<ul style="list-style-type: none"> ● If you become pregnant while you are taking this medicine or within 6 months of stopping this medicine, tell your doctor immediately. ● If you are a man and your partner becomes pregnant while you are taking this medicine or within 3 months of stopping this medicine, tell your doctor immediately.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not take LYNPARZA tablets 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 LYNPARZA tablets or lower the dosage without checking with your doctor.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● LYNPARZA tablets may cause dizziness and tiredness in some

	<p>people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.</p>
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • Keep your tablets in a cool, dry place where the temperature stays below 30°C. • Keep your tablets in the pack until it is time to take them.

For more information, see Section [5. What should I know while using LYNPARZA tablets?](#) in the full CMI.

6. Are there any side effects?

Some of the most common side effects are diarrhoea, nausea, vomiting, indigestion, pain in the stomach area under the ribs, loss of appetite, change in taste of food, cough, headache, dizziness and tiredness. Serious side effects include shortness of breath, tightness of the chest, wheezing, coughing 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

LYNPARZA® tablets

Active ingredient(s): olaparib

Consumer Medicine Information (CMI)

This leaflet provides important information about using LYNPARZA tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LYNPARZA tablets.**

Where to find information in this leaflet:

- [1. Why am I using LYNPARZA tablets?](#)
- [2. What should I know before I use LYNPARZA tablets?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use LYNPARZA tablets?](#)
- [5. What should I know while using LYNPARZA tablets?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using LYNPARZA tablets?

LYNPARZA tablets contain the active ingredient olaparib. LYNPARZA tablets belong to a group of medicines called PARP (Poly (ADP-Ribose) Polymerase enzymes) inhibitors. 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 by looking for faulty DNA repair genes such as BRCA (BReast CAncer) genes.

LYNPARZA tablets are used:

- to treat a type of ovarian cancer (BRCA-mutated) that is newly diagnosed. It is used once the cancer has responded to treatment with standard platinum-based chemotherapy. A test is used to determine whether you have BRCA-mutated ovarian cancer.
- to treat ovarian cancer that has recurred and it has responded to previous treatment with platinum-based chemotherapy.
- in combination with another anti-cancer medicine called bevacizumab to treat ovarian cancer. These medicines are used together once the cancer has responded to the first treatment with standard platinum-based chemotherapy
- to treat a type of breast cancer (germline BRCA-mutated, human epidermal growth factor receptor 2-negative (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 determine if you have germline BRCA mutated breast cancer.
- To treat 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. A test is used to determine whether you have BRCA-mutated breast cancer.

- to treat a type of pancreatic cancer (germline BRCA mutated) which has spread beyond the original tumour. It is used if the cancer has not progressed after treatment with chemotherapy. A test is used to determine whether you have germline BRCA-mutated pancreatic cancer.
- to treat a type of prostate cancer (BRCA-mutated) which has spread beyond the original tumour and no longer responds to medical or surgical treatment that lowers testosterone. You should have already received certain hormonal treatments such as abiraterone acetate or enzalutamide. A test is used to determine whether you have this type of prostate cancer.
- in combination with another anti-cancer medicine called abiraterone, together with the steroid medicine, prednisone or prednisolone to treat a type of prostate cancer (BRCA-mutated) which has spread beyond the original tumour and no longer responds to medical or surgical treatment that lowers testosterone. A test is used to determine whether you have this type of prostate 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 anti-cancer medicines, ask your doctor.

2. What should I know before I use LYNPARZA tablets?

Warnings

Do not use LYNPARZA tablets if:

- you are allergic to olaparib, or 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 in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions, including problems with your kidneys or liver (renal or hepatic impairment) and problems with your blood (e.g. low red blood cell counts, low white blood cell counts or low platelet counts).
- take any medicines for any other condition.

Tell your doctor 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.

Tell your doctor 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).

Talk to your doctor 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 problem with your liver.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or if you (man or women) are planning to have a baby.

It may affect your developing baby if you take it during pregnancy.

Whether you are a man or women, your doctor will advise you to use an effective form of contraception while taking LYNPARZA and for at least 6 months for women and 3 months for men after stopping treatment.

Male patients must use a condom whilst taking LYNPARZA and for 3 months after receiving the last dose when having sexual intercourse with a female partner, even if they are pregnant. Your female partner must also use a suitable method of contraception.

Male patients must not donate sperm whilst taking LYNPARZA and for 3 months after receiving the last dose.

Do not breast-feed if you are taking this medicine.

It is not known if the active ingredient in LYNPARZA tablets pass into breast milk. Breast-feeding mothers are advised not to breast-feed during treatment with LYNPARZA tablets 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 have not been established.

3. What if I am taking other medicines?

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

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, etravirine and efavirenz
- medicines used to treat epilepsy with active ingredients such as phenytoin, carbamazepine
- 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, digoxin, furosemide, valsartan and verapamil
- medicines called statins used to treat high cholesterol such as rosuvastatin and atorvastatin
- medicines used to treat diabetes, such as glibenclamide and metformin
- bosentan, a medicine used to treat high blood pressure in the lungs

- medicines used to suppress the immune system, such as ciclosporin, tacrolimus and sirolimus
- fentanyl, a medicine used to treat cancer pain
- methotrexate, a medicine used to treat cancer, rheumatoid arthritis and psoriasis
- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these could interact with LYNPARZA tablets.

4. How do I use LYNPARZA tablets?

How much to take / use

- The usual dose is two 150 mg tablets taken twice each day (a total of 4 tablets each day).
- Your doctor may prescribe a different dose if you have problems with your kidneys, or are taking certain medicines that may interact with LYNPARZA tablets or if you experience certain side effects while you are taking LYNPARZA tablets.
- Follow the instructions provided and use LYNPARZA tablets until your doctor tells you to stop. It is important to keep taking your medicine even if you feel well.

When to take / use LYNPARZA tablets

- LYNPARZA tablets should be used at 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.
- LYNPARZA tablets can be taken with or without food.

How to take LYNPARZA tablets

- Swallow the tablets whole with a glass of water. Do not chew, crush, dissolve or divide the tablets as this may affect how quickly the drug gets into your body.

If you forget to use LYNPARZA tablets

LYNPARZA tablets should be used regularly at the same time each day. If you miss your dose at the usual time, 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 tablets.**

If you are not sure what to do, ask your doctor.

If you use too much LYNPARZA tablets

If you think that you have used too much LYNPARZA tablets, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using LYNPARZA tablets?

Things you should 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 or within 6 months after receiving the last dose of LYNPARZA, tell your doctor immediately. If you are a man and your partner becomes pregnant while you are taking this medicine or within 3 months of stopping this medicine, tell your doctor immediately. See additional information under Section [2. What should I know before I use LYNPARZA tablets?](#)

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 should not do

- Do not take LYNPARZA tablets 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LYNPARZA tablets affect you.

LYNPARZA tablets 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.

Looking after your medicine

- **Keep LYNPARZA tablets in the blister pack until it is time to take them.** If you take the tablets out of the blister they may not keep well.
- **Keep LYNPARZA tablets below 30°C.**

Store LYNPARZA tablets in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- **in the bathroom or near a sink, or**
- **in the car or on window sills.**

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● diarrhoea. If it gets severe, tell you doctor straight away.● feeling or being sick (nausea or vomiting)● indigestion or heartburn● pain in the stomach area under the ribs● loss of appetite● change in taste of food (if it worries you)● sore mouth● cough● headache● dizziness● tiredness or weakness (fatigue)● rash and itchy rash on swollen, reddened skin	<p>Speak to your doctor if you have any of these side effects and they worry you or if they get worse.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">● shortness of breath, tightness of the chest, wheezing, coughing or difficulty in 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.● 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.● inflammation of the lungs, which can cause coughing with a fever and difficulty breathing (pneumonitis).● signs of liver problems, such as yellowing of	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>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.</p>	

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 the number of white blood cells which can be associated with fever or infection
- increase in blood creatinine which can mean your kidneys are not working as well
- decrease in the number of platelets, which can result in bruising or bleeding for longer than normal if injured.

These conditions may also be life-threatening, especially if not treated.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Your doctor may prescribe other medicines to control unwanted side effects.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What LYNPARZA tablets contains

Active ingredient (main ingredient)	olaparib
Other ingredients	copovidone

(inactive ingredients)	colloidal anhydrous silica mannitol sodium stearyl fumarate hypromellose macrogol 400 titanium dioxide iron oxide yellow iron oxide black (150 mg tablet only)
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Do not take this medicine if you are allergic to any of these ingredients.

What LYNPARZA tablets look like

LYNPARZA 100 mg tablet is a yellow to dark yellow, oval, bi-convex, film-coated tablet, marked with 'OP100' on one side and plain on the other. (AUST R 288613)

LYNPARZA 150 mg tablet is a green to green/grey oval, bi-convex, film-coated tablet, marked with 'OP150' on one side and plain on the other. (AUST R 288614)

LYNPARZA tablets are available in blisters containing 56 film-coated tablets, packed in cartons containing 7 blisters of 8 tablets.

Who distributes LYNPARZA tablets

AstraZeneca Pty Ltd

ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

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