

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **LYNPARZA**®

Olaparib Tablets

This patient medication information is written for the person who will be taking **LYNPARZA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **LYNPARZA**, talk to a healthcare professional.

Serious warnings and precautions box

- Only a healthcare professional who has experience treating cancer should treat you with LYNPARZA.
- **Myelodysplastic Syndrome or Acute Myeloid Leukemia** is a problem with the bone marrow. You may have abnormal red, white or platelet cell counts. This is serious and can lead to death.
- **Pneumonitis** is lung inflammation. It makes it hard for the lungs to absorb oxygen and remove carbon dioxide. It is serious and can lead to death or require hospital treatment.
- LYNPARZA can harm your unborn baby if you take it while you are pregnant.

What LYNPARZA is used for:

Breast Cancer

- Human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has not spread to other parts of the body in adults with mutations in their *BRCA* genes. LYNPARZA is given after surgery. Patients should have received chemotherapy before or after surgery to remove the tumour.
- Breast cancer that has spread outside the breast (metastasized) in adults with mutations in their *BRCA* genes and who have already had chemotherapy. Patients may have also had hormone therapy for their breast cancer.

Ovarian Cancer

- Cancer of the ovaries and some other closely related cancers in adults. When the cancer responds to chemotherapy that contains platinum, LYNPARZA helps to keep that response.
- LYNPARZA is an add-on treatment used in patients who receive another anti-cancer medicine called bevacizumab. This is used for the treatment of advanced cancer of the ovaries and some other closely related cancers with mutations in their *BRCA* genes and/or a positive laboratory tumour test for genomic instability called HRD. These medicines are used together once the cancer has responded to the first treatment with platinum-based chemotherapy and bevacizumab.

Prostate Cancer

- LYNPARZA is used in combination with another anti-cancer medicine called abiraterone, together with the steroid medicine prednisone or prednisolone. This combination is for the treatment of prostate cancer that has spread outside the prostate (metastasized) in adults with mutations in their *BRCA* genes and for whom chemotherapy is not recommended.
- Prostate cancer that has spread outside the prostate (metastasized) in adults with mutations in their *BRCA* or *ATM* genes. The prostate cancer no longer responds to drugs or surgery to lower testosterone. Patients should have already had certain new hormonal treatments.

Pancreatic Cancer

- Pancreatic cancer that has spread outside the pancreas (metastasized) in adults with mutations in their *BRCA* genes. When the cancer has not worsened after chemotherapy that contains platinum, LYNPARZA helps to maintain that response.

If you have mutations (changes) in your *BRCA* genes you are at higher risk of getting certain types of cancer. The *ATM* gene is another gene that can increase your chances of getting certain types of cancer if it has mutations. A test may be done before you start taking LYNPARZA to see if you have mutations in your *BRCA* or *ATM* genes.

How LYNPARZA works:

LYNPARZA is a type of drug called a PARP (poly [adenosine diphosphate-ribose] polymerase) inhibitor. PARP inhibitors can destroy cancer cells that are not able to repair damage to their DNA (genes).

In some patients with breast cancer, cancer of the ovaries, pancreatic cancer, prostate cancer and some other closely related cancers, there are mutations in genes such as the *BRCA* (breast cancer) or *ATM* genes. For breast cancer and pancreatic cancer, LYNPARZA works in patients with *BRCA* mutations. For cancer of the ovaries and some other closely related cancers, LYNPARZA works in patients with and without *BRCA* mutations. For prostate cancer, LYNPARZA works in patients with mutations in either the *BRCA* or *ATM* genes. A test is used to see if you have mutations in your *BRCA* or *ATM* genes.

When LYNPARZA is used in combination with abiraterone (an androgen receptor signalling inhibitor), the combination may help enhance the anti-cancer effect in prostate cancer cells with faulty DNA repair genes (e.g., *BRCA* genes).

The ingredients in LYNPARZA:

Medicinal ingredients: Olaparib

Non-medicinal ingredients: Colloidal silicon dioxide, copovidone, hypromellose, iron oxide black (150 mg tablet only), iron oxide yellow, macrogol 400, mannitol, sodium stearyl fumarate, titanium dioxide.

LYNPARZA comes in the following dosage forms:

Film-coated tablets: 100 mg and 150 mg

Do not use LYNPARZA if:

- You are allergic to olaparib or any of the other ingredients in this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LYNPARZA. Talk about any health conditions or problems you may have, including if you:

- have moderate or severe kidney disease.
- have severe liver disease.
- have clots in your blood vessels.

Other warnings you should know about:

Female Patients:

- If you are pregnant, or still able to get pregnant and/or breast-feed, there are specific risks you must discuss with your healthcare professional.
- Avoid becoming pregnant while taking LYNPARZA. It may harm your unborn baby or make you lose the pregnancy. You should use two effective methods of birth control while taking LYNPARZA.
- Keep using birth control for 6 months after taking your last dose of LYNPARZA. If you do become pregnant while taking LYNPARZA, tell your healthcare professional right away.
- It is not known if LYNPARZA causes hormonal birth control to not work as well. Please tell your healthcare professional if you are taking a hormonal birth control. They may recommend the addition of a non-hormonal birth control method. If you have hormone dependent cancer, they may recommend two non-hormonal birth control methods.
- **For women who can get pregnant:** a pregnancy test should be done: before you start to take LYNPARZA; regularly while you are taking it; and for 6 months after taking your last dose.
- LYNPARZA may pass into breast milk. Do not breast-feed while you are taking LYNPARZA and for 1 month after taking your last dose of LYNPARZA. If you are planning to breast-feed, tell your healthcare professional.

Male Patients:

- Use a condom when having sexual intercourse with a woman (even if she is pregnant). The condom must be used:
 - while you are taking LYNPARZA, and
 - for 3 months after you take your last dose of LYNPARZA.
- Your female partner must also use an effective method of birth control.
- Do not donate sperm while taking LYNPARZA and for 3 months after stopping LYNPARZA.

Driving and using machines: Before you do tasks which may require special attention, wait until you know how you respond to LYNPARZA. If you feel dizzy, weak, or tired, do not drive or use tools or machines.

Blood tests: LYNPARZA can cause abnormal blood test results. Your healthcare professional will test your blood every month for the first year of treatment and periodically thereafter. Your healthcare professional will tell you if your test results are abnormal and if you need treatment to correct these side effects.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Some medicines can affect the level of LYNPARZA in your body. Also, LYNPARZA can affect the way some other medicines work. The medicines listed here may not be the only ones that could interact with LYNPARZA.

The following may interact with LYNPARZA:

- Itraconazole, fluconazole - used to treat fungal infections.
- Telithromycin, clarithromycin, erythromycin, ciprofloxacin - used to treat bacterial infections.
- Ritonavir, nelfinavir, indinavir, saquinavir, nevirapine, cobicistat, boceprevir, telaprevir, etravirine, efavirenz, amantadine - used to treat viral infections, primarily HIV.
- Rifampicin, rifapentine, rifabutin - used to treat bacterial infections, primarily tuberculosis.
- Phenytoin, carbamazepine, phenobarbital - used to treat seizures and epilepsy.
- St John's Wort (*Hypericum perforatum*) - an herbal remedy used mainly for depression.
- Bupropion - mainly used for depression and smoking cessation.
- Diltiazem, furosemide, valsartan, verapamil - used to treat heart conditions or high blood pressure.
- Bosentan - used to treat pulmonary artery hypertension.
- Statins e.g. simvastatin - used to lower blood cholesterol levels.
- 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, cimetidine - used to treat stomach problems.
- Cyclosporine, sirolimus, tacrolimus - used to suppress the immune system.
- Cisplatin - used to treat cancer.
- Methotrexate - used to treat cancer, rheumatoid arthritis and psoriasis.
- Modafinil - used to treat a sleep disorder called narcolepsy.
- Midazolam - used to produce sleepiness and drowsiness.

Do not eat or drink any products or juices containing grapefruit, star fruit, pomegranate or Seville oranges while taking LYNPARZA. They can affect the way the medicine works.

How to take LYNPARZA:

- Always take LYNPARZA exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Swallow LYNPARZA tablets whole. Do NOT chew, crush, dissolve or divide the tablets. This may affect how quickly the drug gets into your body.
- Take LYNPARZA at about the same time each morning and evening.
- LYNPARZA can be taken with or without food.
- If you are taking LYNPARZA for prostate cancer:
 - You should also receive gonadotropin-releasing hormone (GnRH) analog therapy at the same time unless you had a surgery to lower testosterone in your body.
- If you are taking LYNPARZA for early breast cancer and you have hormone receptor-positive disease, you should continue to take hormonal therapy during your treatment with LYNPARZA.
- Never take more than 4 tablets in a day.
- Your healthcare professional will tell you when to start LYNPARZA after you finish your chemotherapy treatment.
- Your healthcare professional will decide how long you stay on LYNPARZA treatment.

Usual Dose:

Adult Daily Dose 600 mg: take two 150 mg tablets twice a day.

Your healthcare professional may interrupt or reduce your dose. This may happen if you:

- have problems with your kidneys.
- are taking medicines that may interact with LYNPARZA.
- have certain side effects while taking LYNPARZA.

Taking LYNPARZA with Abiraterone and Prednisone or Prednisolone:

Adult Daily Dose of Abiraterone: 1000 mg once daily.

Adult Daily Dose of Prednisone or Prednisolone: 5 mg twice daily.

Reduced Total Daily Doses:

Adult Daily Dose 500 mg: take one 150 mg tablet and one 100 mg tablet twice a day.

Adult Daily Dose 400 mg: take two 100 mg tablets twice a day.

Adult Daily Dose 300 mg: take one 150 mg tablet twice a day.

Adult Daily Dose 200 mg: take one 100 mg tablet twice a day.

Overdose:

If you think you, or a person you are caring for, have taken too much LYNPARZA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms

Missed Dose:

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

Possible side effects from using LYNPARZA:

These are not all the possible side effects you may feel when taking LYNPARZA. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Changes in the way food tastes
- Constipation
- Cough
- Feeling dizzy
- Feeling tired or weak
- Fever
- Headache
- Indigestion or heartburn
- Itchy rash on swollen, reddened skin (dermatitis)
- Loss of appetite
- Pain in the stomach area under the ribs
- Rash
- Shortness of breath

It is common to experience nausea and vomiting at the start of your treatment. These side effects may improve over time. Ask your healthcare professional how to treat these side effects.

Serious side effects and what to do about them			
Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Anemia (low red blood cells): Being short of breath, feeling very tired, having pale skin, fast heartbeat, loss of energy, or weakness.		✓	
Neutropenia or Leukopenia (low white blood cells: neutrophils and leukocytes): Fever or infection, fatigue, aches and pains, and flu-like symptoms.		✓	
Nausea and Vomiting: Feeling sick. Being sick or throwing up.	✓		
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder and urethra): Pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine.		✓	
COMMON			
Stomatitis (mouth sores, inflammation of the mouth) or Mucosal Inflammation (inflammation of the moist body surfaces): Red, sore or swollen mouth, lips, gums, nose or eyes. Ulcers can occur.	✓		
Myelodysplastic Syndrome or Acute Myeloid Leukemia (a group of diseases in which the body produces large numbers of abnormal blood cells): Fever, infection, bruising or bleeding easily, breathlessness, blood in urine or stool.			✓
Cystitis (inflammation of the bladder): Urge to urinate more often, uncomfortable or painful urination, cloudy, dark or strong smelling urine, blood in urine.	✓		
Lymphopenia (low white blood cells: lymphocytes): Get infections more easily.		✓	
Pneumonia (infection in the lungs): Cough which may produce phlegm, fever, chills, shortness of breath, difficult and painful breathing, nausea, vomiting or diarrhea, chest pain when you breathe or cough, confusion.		✓	

Serious side effects and what to do about them			
Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Pulmonary embolism (blood clot in the lung): Shortness of breath, chest pain particularly on breathing in, breathing that is more rapid than normal or heart beats faster than normal and coughing up blood.			✓
Thrombosis (clot in a blood vessel): Swelling and pain in one part of the body, usually in the leg (venous thrombosis).			✓
Thrombocytopenia (low blood platelets): Bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness.		✓	
UNCOMMON			
Allergic Reactions: Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
Diarrhea: Severe, at least 3 loose or liquid bowel movements in a day.	✓		
Pneumonitis (lung inflammation): New or worsening shortness of breath, difficulty breathing, cough, wheezing or fever.			✓
RARE			
Angioedema (swelling of the tissue under the skin or other body tissue).		✓	
Erythema nodosum (painful inflammation in a part of the fatty layer of the skin): Red and painful lumps usually in the legs		✓	
UNKNOWN			
Hepatotoxicity (liver problems): yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness, unexplained loss of appetite.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store between 2 - 30°C.
- Store in the original package in order to protect from moisture.
- Do not use after the expiry date stated on the bottle after EXP. The expiry date refers to the last day of that month.
- 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.

Keep out of reach and sight of children.

If you want more information about LYNPARZA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.astrazeneca.ca), or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to date version can be found at www.astrazeneca.ca.

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