

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

 LYNPARZA®

Olaparib Capsules

Read this carefully before you start taking LYNPARZA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about LYNPARZA.

To decrease the **Risk of Medication Errors**, all patients on LYNPARZA capsules should register in the **AstraZeneca Oncology Patient Support Program**. Your healthcare professional will help you register. The program will help you take LYNPARZA capsules correctly. It will give you information and answer any questions you may have.

Serious Warnings and Precautions

- Only a doctor who has experience treating cancer should treat you with this drug.
- **Myelodysplastic Syndrome or Acute Myeloid Leukemia** is a problem with the bone marrow. You may have low red, white or platelet cell counts. This is serious and can lead to death.
- **Pneumonitis** is a 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.
- **Risk of Medication Errors:** 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.
- LYNPARZA can harm your unborn baby if you take it while you are pregnant.

What are LYNPARZA capsules used for?

LYNPARZA is used in adults to treat cancer of the ovaries. It can also treat some other closely related cancers. When your cancer responds to chemotherapy, LYNPARZA helps to keep that response.

LYNPARZA capsules should be used in a specific group of ovarian cancer patients. These people have mutations (changes) in certain genes called *BRCA* (known as the breast cancer gene). A test is used to determine whether you have a mutation of your *BRCA* genes.

How does LYNPARZA work?

LYNPARZA is a type of drug called a PARP (poly [adenosine diphosphate-ribose] polymerase) inhibitor. In patients who have mutations (changes) in certain genes called *BRCA* (known as the breast cancer gene), LYNPARZA stops cancer cells from repairing damage to their DNA, which helps to kill the cancer cells.

What are the ingredients in LYNPARZA capsules?

Medicinal ingredients: olaparib

Non-medicinal ingredients: gellan gum, hypromellose, iron oxide black, lauroyl macrogol glycerides, potassium acetate, shellac, titanium dioxide.

LYNPARZA comes in the following dosage forms:

Capsule: 50 mg

PLEASE NOTE: LYNPARZA is also available as a 100 mg and 150 mg **tablet**.

Risk of Medication Error: 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.

Do not use LYNPARZA if:

- You are allergic to olaparib or any of the other ingredients of 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 or liver disease.

Other warnings you should know about:

- 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 child or make you lose the pregnancy. You should use effective methods of birth control while taking LYNPARZA. Keep using birth control for 1 month after taking your last dose of LYNPARZA. If you do become pregnant while taking LYNPARZA, tell your doctor right away.
- **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 one month after taking your last dose.
- LYNPARZA may pass into breast milk. Do not breast-feed while you are taking LYNPARZA and for one month after taking your last dose of LYNPARZA. If you are planning to breast-feed, tell your doctor.

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.

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:

- ketoconazole, itraconazole, fluconazole - used to treat fungal infections.
- telithromycin, clarithromycin, erythromycin, ciprofloxacin - used to treat bacterial infections.
- protease inhibitors boosted with ritonavir or cobicistat, nelfinavir, indinavir, saquinavir, boceprevir, telaprevir, nevirapine, efavirenz, etravirine, amantadine - used to treat viral infections, including HIV.
- rifampicin, rifapentine, rifabutin - used to treat bacterial infections, including tuberculosis (TB).
- phenytoin, carbamazepine, phenobarbital - used to treat fits (seizures) and epilepsy.
- St John's Wort (*Hypericum perforatum*) - an herbal remedy used mainly for depression.
- bupropion - mainly used for depression and smoking cessation.
- modafinil - used to treat a sleep disorder called narcolepsy.
- 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 disorders.
- 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.
- midazolam - used to produce sleepiness and drowsiness.

Do not take LYNPARZA with any other drugs that treat cancer.

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

How to take LYNPARZA capsules:

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

Be sure the doctor has ordered CAPSULES for you.

- Take at least one hour after eating food. Do not eat for up to 2 hours after taking LYNPARZA capsules.
- Take at about the same time each morning and evening.
- Swallow whole. Do NOT chew, crush, dissolve or divide the capsules.
- Start taking LYNPARZA within 8 weeks of your last dose of platinum containing chemotherapy.

Recommended Total Daily Dose:

Usual adult dose 800 mg: Take eight 50 mg capsules (for a dose of 400 mg) by mouth twice a day. This is a total of 16 capsules each day, 8 in the morning and 8 in the evening. Your doctor 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.

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

Reduced Total Daily Doses for Capsules:

Adult Daily Dose 600 mg: take as six 50 mg capsules twice a day.

Adult Daily Dose 400 mg: take as four 50 mg capsules twice a day.

Adult Daily Dose 300 mg: take as three 50 mg capsules twice a day.

Adult Daily Dose 200 mg: take as two 50 mg capsules twice a day.

Overdose:

If you think you have taken too much LYNPARZA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no 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 a forgotten dose.

What are 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:

- headache
- feeling dizzy

- loss of appetite
- feeling tired or weak
- changes in the way food tastes
- indigestion or heartburn
- pain in the stomach area under the ribs
- rash
- itchy rash on swollen, reddened skin (dermatitis)
- cough

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

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

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking 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, weakness.		x	
Nausea and Vomiting: Feeling sick. Being sick or throwing up.	x		
COMMON			
Neutropenia or leukopenia (Low white blood cells: neutrophils and leukocytes): Fever or infection, fatigue, aches and pains, and flu-like symptoms.		x	
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.	x		

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Diarrhea: Severe, at least 3 loose or liquid bowel movements in a day.	x		
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.			x
Thrombocytopenia (Low blood platelets): Bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness.		x	
UNCOMMON			
Lymphopenia (low white blood cells: lymphocytes): Get infections more easily.		x	
Allergic reactions: Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			x
Pneumonitis (lung inflammation): New or worsening shortness of breath, cough, wheezing or fever.		x	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) 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 in the refrigerator between 2 - 8°C. You can keep LYNPARZA capsules at room temperature (up to 25°C) for up to 3 months if needed. You must throw away any unused capsules after 3 months if you store them at room temperature.
- Do not freeze.
- 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
- This Patient Medication Information leaflet provides you with the most current information at the time of printing. Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (www.healthcanada.gc.ca); the manufacturer's website (www.astrazeneca.ca), or by calling 1-800-668-6000.

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