

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

 LYNPARZA®

Olaparib Tablets

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**.

What are LYNPARZA tablets used for?

LYNPARZA is used to treat a type of breast cancer that has spread outside the breast in adults who have inherited changes (mutations) in the *BRCA* genes. *BRCA* genes are known as the breast cancer genes. A test is used to find out if there is a mutation in your breast cancer genes. To receive LYNPARZA for your breast cancer, you must have this mutation and have had previous chemotherapy for your breast cancer. You may also have had hormone therapy for your breast cancer.

- In patients with breast cancer, LYNPARZA has been approved **without conditions**. This means it has passed Health Canada's review and can be bought and sold in Canada.

LYNPARZA is also used to treat cancer of the ovaries and some other closely related cancers. When the cancer responds to chemotherapy that contains platinum, LYNPARZA helps to keep that response. LYNPARZA works in patients with and without mutations in *BRCA* genes. A test is used to find out if there is a mutation in your *BRCA* genes. In patients:

- *Without BRCA mutation*
LYNPARZA has been approved **with conditions (NOC/c)**. This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.
- *With BRCA mutation*
LYNPARZA has been approved **without conditions**. This means it has passed Health Canada's review and can be bought and sold in Canada.

LYNPARZA is used to treat a type of pancreatic cancer that has spread outside the pancreas in adults who have inherited changes (mutations) in their *BRCA* genes. When the cancer has not worsened after chemotherapy that contains platinum, LYNPARZA helps to maintain that response. A test is used to find out if there is a mutation in your *BRCA* genes. In patients with pancreatic cancer that has spread outside the pancreas, LYNPARZA has been approved **without conditions**. This means it has passed Health Canada's review and can be bought and sold in Canada.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada. Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

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 a 50 mg capsule. The doses of LYNPARZA tablets and capsules are not the same. Taking the wrong dose or a capsule instead of a tablet could lead to LYNPARZA not working properly or to more side effects. Do not take more than 4 tablets per day.
- LYNPARZA can harm your unborn baby if you take it while you are pregnant.

How does LYNPARZA work?

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 and some other closely related cancers or pancreatic cancer, there are mutations in genes such as the *BRCA* (breast cancer) 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. A test is used to find out whether you have a mutation of your *BRCA* genes.

What are the ingredients in LYNPARZA tablets?

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:

Tablets: 100 mg and 150 mg

PLEASE NOTE: LYNPARZA is also available as a 50 mg **capsule**.

Risk of Medication Error: The doses of LYNPARZA tablets and capsules are not the same. Taking the wrong dose or a capsule instead of a tablet could lead to LYNPARZA not working properly or to more side effects. Do NOT take more than 4 tablets per day.

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 or liver disease.

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 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 1 month after taking your last dose of LYNPARZA. If you are planning to breast-feed, tell your doctor.

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.

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 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.
- Modafinil - used to treat a sleep disorder called narcolepsy.
- 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 tablets:

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 TABLETS for you.

- Swallow whole. Do NOT chew, crush, dissolve or divide the tablets. This may affect how quickly the drug gets into your body.
- Take at about the same time each morning and evening.
- Take with or without food.
- Never take more than 4 tablets in a day.
- Your doctor will tell you when to start LYNPARZA after you finish your chemotherapy treatment.
- Your doctor will decide how long you stay on LYNPARZA treatment.

Recommended Total Daily Dose for Tablets:

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

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.

Reduced Total Daily Doses for Tablets:

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 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 forgotten tablets.

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
- Fever
- Shortness of breath
- Constipation

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, or weakness.		X	
Neutropenia or Leukopenia (low white blood cells: neutrophils and leukocytes): Fever or infection, fatigue, aches and pains, and flu-like symptoms.		X	
Thrombocytopenia (low blood platelets): Bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness.		X	
Nausea and Vomiting: Feeling sick. Being sick or throwing up.	X		
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.		X	
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.	X		
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
Cystitis (inflammation of the bladder): Urge to urinate more often, uncomfortable or painful urination, cloudy, dark or strong smelling urine, blood in urine.	X		
Lymphopenia (low white blood cells: lymphocytes): Get infections more easily.		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	
UNCOMMON			
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.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • 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. <p><i>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.</i></p>
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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 this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); 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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