

Medication Guide

Lynparza (Lin-par-zah) (olaparib) capsules

Read this Medication Guide before you start taking Lynparza and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about Lynparza?

Lynparza may cause serious side effects that can lead to death, including:

Bone marrow problems called Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML). Some people who have ovarian cancer or who have received previous treatment with chemotherapy or certain other medicines for their cancer have developed MDS or AML during treatment with Lynparza. If you develop MDS or AML, your healthcare provider will stop treatment with Lynparza.

Symptoms of low blood cell counts are common during treatment with Lynparza, but can be a sign of serious bone marrow problems, including MDS or AML. Symptoms may include:

- weakness
- weight loss
- fever
- frequent infections
- blood in urine or stool
- shortness of breath
- feeling very tired
- bruising or bleeding more easily

Your healthcare provider will do blood tests to check your blood cell counts:

- before treatment with Lynparza
- every month during treatment with Lynparza
- weekly if you have low blood cell counts that last a long time. Your healthcare provider may stop treatment with Lynparza until your blood cell counts improve.

Lung problems (pneumonitis). Tell your healthcare provider if you have any new or worsening symptoms of lung problems, including shortness of breath, fever, cough, or wheezing. Your healthcare provider may do a chest x-ray if you have any of these symptoms. Your healthcare provider may temporarily stop treatment or completely stop treatment if you develop pneumonitis.

Tell your healthcare provider if you have any of the symptoms above during treatment with Lynparza.

What is Lynparza?

Lynparza is a prescription medicine used to treat women with advanced ovarian cancer who:

- have received previous treatment with 3 or more prior chemotherapy medicines or a combination of chemotherapy medicines for their cancer, **and**
- have a certain type of abnormal inherited BRCA gene.

Your healthcare provider will perform a test to make sure that Lynparza is right for you.

It is not known if Lynparza is safe and effective in children.

What should I tell my healthcare provider before taking Lynparza?

Before you take Lynparza, tell your healthcare provider if you:

- have lung or breathing problems
- have liver problems
- have kidney problems
- are pregnant or plan to become pregnant. **Lynparza can harm your unborn baby and may cause loss of pregnancy (miscarriage).** You should not become pregnant during treatment with Lynparza. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
 - Females who are able to become pregnant should use effective birth control (contraception) during treatment with Lynparza and for at least 1 month after receiving the last dose of Lynparza.
 - Talk to your healthcare provider about birth control methods that may be right for you.
 - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Lynparza.
- are breastfeeding or plan to breastfeed. It is not known if Lynparza passes into your breast milk. You and your healthcare provider should decide if you will take Lynparza or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking Lynparza and certain other medicines may affect how Lynparza works and may cause side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take Lynparza?

- Take Lynparza exactly as your healthcare provider tells you.
- Your healthcare provider may temporarily stop treatment with Lynparza or change your dose of Lynparza if you have side effects.
- Take Lynparza 2 times a day.
- Swallow Lynparza capsules whole. Do not chew, dissolve, or open the capsules.
- Do not take Lynparza capsules if they look damaged or show signs of leakage.
- If you miss a dose of Lynparza, take your next dose at your usual scheduled time. Do not take an extra dose to make up for a missed dose.
- If you take too much Lynparza, call your healthcare provider or go to the nearest emergency room right away.

What should I avoid while taking Lynparza?

- Avoid grapefruit, grapefruit juice and Seville oranges during treatment with Lynparza. Grapefruit and Seville oranges may increase the level of Lynparza in your blood.

What are the possible side effects of Lynparza?

Lynparza may cause serious side effects.

See “What is the most important information I should know about Lynparza?”

The most common side effects of Lynparza are:

- nausea or vomiting. Tell your healthcare provider if you get nausea or vomiting. Your healthcare provider may prescribe medicines to treat these symptoms.
- tiredness or weakness
- diarrhea
- indigestion or heartburn
- headache
- loss of appetite
- changes in the way food tastes
- changes in kidney function blood test
- sore throat or runny nose
- upper respiratory infection
- cough
- pain in the joints, muscles, and back
- rash
- pain or discomfort in the stomach area

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Lynparza. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Lynparza?

- Store Lynparza at room temperature, between 68 to 77°F (20 to 25°C).
- Do not store Lynparza at temperatures greater than 104°F (40°C). Do not take Lynparza if you think it may have been stored at a temperature greater than 104°F (40°C).

Keep Lynparza and all medicines out of the reach of children.

General information about the safe and effective use of Lynparza

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Lynparza for a condition for which it was not prescribed. Do not give Lynparza to other people, even if they have the same symptoms you have. It may harm them.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Lynparza that is written for health professionals.

For more information, call 1-800-236-9933 or go to www.Lynparza.com.

What are the ingredients in Lynparza?

Active ingredient: olaparib

Inactive ingredients:

Capsule contains: lauroyl polyoxylglycerides

Capsule shell contains: hypromellose, titanium dioxide, gellan gum, potassium acetate

Capsule printing ink contains: shellac, ferrousferrous oxide

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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