

**Medication Guide**  
**Lynparza® (Lin-par-zah)**  
**(olaparib)**  
**tablets**

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

**Lynparza may cause serious side effects, including:**

- **Bone marrow problems called Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML).** Some people who have received previous treatment with chemotherapy, radiotherapy or certain other medicines for their cancer have developed MDS or AML during treatment with Lynparza. MDS or AML may lead to death. 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 easilyYour 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.
- **Lung problems (Pneumonitis).** Lynparza can cause serious lung problems that can lead to death. 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.
- **Blood clots (Venous Thromboembolism, [VTE]).** Some people may develop a blood clot in a deep vein, usually in the leg (venous thrombosis), or a clot in the lungs (pulmonary embolism, [PE]) which may be severe or lead to death. Tell your healthcare provider right away if you have any symptoms such as pain or swelling in an extremity, shortness of breath, chest pain, breathing that is more rapid than normal (tachypnea), or heart beats faster than normal (tachycardia). Your healthcare provider will monitor you for these symptoms and may prescribe blood thinner medicine.
- **Liver problems, including Drug-Induced Liver Injury (DILI).** People taking Lynparza may develop liver problems which may be severe and can lead to death. Your healthcare provider should do blood tests before and during your treatment with Lynparza. Tell your healthcare provider right away if you notice discomfort on the right side of your stomach-area (abdominal), dark or “tea-colored” urine, or yellowing of your skin or the whites of your eyes (jaundice).

Your healthcare provide may change your dose, temporarily stop, or permanently stop treatment with Lynparza if you get certain side effects.

See “**What are the possible side effects of LYNPARZA?**” for more information about side effects.

## What is Lynparza?

Lynparza is a prescription medicine used to treat adults who have:

- ovarian, fallopian tube, or primary peritoneal cancer:
  - that is advanced and has a certain type of inherited (germline) or acquired (somatic) abnormal *BRCA* gene. Lynparza is used as maintenance treatment after the cancer has responded to your first treatment with platinum-based chemotherapy.
  - in combination with another anti-cancer medicine called bevacizumab when your cancer is advanced and homologous recombination deficiency (HRD) positive, which is identified by a certain type of abnormal *BRCA* gene or a positive laboratory tumor test for genomic instability. Lynparza is used as maintenance treatment after the cancer has responded to your first treatment with platinum-based chemotherapy.
  - that has come back and has a certain type of inherited or acquired abnormal *BRCA* gene. Lynparza is used as maintenance treatment after the cancer has responded to treatment with platinum-based chemotherapy.
- human epidermal growth factor receptor 2 (HER2)-negative breast cancer with a certain type of inherited abnormal *BRCA* gene:
  - with a high risk of recurrence. Lynparza is given after surgery (treatment after surgery is called adjuvant therapy). You should have received chemotherapy medicines before or after surgery to remove the tumor.
  - that has spread to other parts of the body (metastatic). You should have received chemotherapy medicines, either before or after your cancer has spread. If you have hormone receptor (HR)-positive breast cancer, you should have either already received hormonal therapy or hormonal therapy is not the right treatment for you.
- pancreatic cancer (adenocarcinoma) that has spread to other parts of the body and has a certain type of abnormal inherited *BRCA* gene. Lynparza is used as maintenance treatment after your cancer has not progressed on at least 16 weeks of your first treatment with platinum-based chemotherapy.
- metastatic castration-resistant prostate cancer (mCRPC):
  - with a certain type of inherited or acquired abnormal homologous recombination repair (HRR) genes. Lynparza is used when the cancer has spread to other parts of the body and no longer responds to a medical or surgical treatment that lowers testosterone and has progressed after treatment with other anti-cancer medicines called enzalutamide or abiraterone.
  - with a certain type of abnormal *BRCA* gene, and the cancer has spread to other parts of the body and no longer responds to a medical or surgical treatment that lowers testosterone. Lynparza is used in combination with another anti-cancer medicine, abiraterone, together with the steroid medicine prednisone or prednisolone.

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.

## Before taking Lynparza, tell your healthcare provider about all of your medical conditions, including if you:

- have lung or breathing problems
- have kidney problems
- are pregnant, become pregnant, or plan to become pregnant. Lynparza can harm your unborn baby and may cause loss of pregnancy (miscarriage).

### Females who are able to become pregnant:

- Your healthcare provider may do a pregnancy test before you start treatment with Lynparza.
- You should use effective birth control (contraception) during treatment with Lynparza and for 6 months after 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 might be pregnant following treatment with Lynparza.

### Males with female partners who are pregnant or able to become pregnant:

- You should use effective contraception during treatment with Lynparza and for 3 months after the last dose of Lynparza.
- Do not donate sperm during treatment with Lynparza and for 3 months after your last dose.
- are breastfeeding or plan to breastfeed. It is not known if Lynparza passes into your breast milk. Do not breastfeed during treatment with Lynparza and for 1 month after receiving the last dose of Lynparza. Talk to your healthcare provider about the best way to feed your baby during this time.

**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.

### How should I take Lynparza?

- Take Lynparza tablets exactly as your healthcare provider tells you.
- Your healthcare provider will decide how long you stay on treatment.
- Do not change your dose or stop taking Lynparza unless your healthcare provider tells you to.
- Take Lynparza by mouth 2 times a day, with or without food.
- Each dose should be taken about 12 hours apart.
- Swallow Lynparza tablets whole. Do not chew, crush, dissolve, or divide the tablets.
- If you are taking Lynparza for early breast cancer and you have HR-positive disease, you should continue to take hormonal therapy during your treatment with Lynparza.
- If you are taking Lynparza for prostate cancer and you are receiving gonadotropin-releasing hormone (GnRH) analog therapy, you should continue with this treatment during your treatment with Lynparza unless you have had a surgery to remove both of your testicles (surgical castration) to lower the amount of testosterone in your body.
- 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 hospital emergency room right away.

### What should I avoid while taking Lynparza?

Avoid grapefruit, grapefruit juice, Seville oranges and Seville orange juice during treatment with Lynparza since they 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 when used alone are:

- |                                  |                               |
|----------------------------------|-------------------------------|
| • tiredness or weakness          | • cough                       |
| • low red blood cell counts      | • low white blood cell counts |
| • diarrhea                       | • shortness of breath         |
| • loss of appetite               | • dizziness                   |
| • headache                       | • indigestion or heartburn    |
| • changes in the way food tastes | • low platelet counts         |

#### The most common side effects of Lynparza when used in combination with bevacizumab are:

- |                             |                               |
|-----------------------------|-------------------------------|
| • tiredness or weakness     | • low white blood cell counts |
| • low red blood cell counts | • urinary tract infection     |
| • diarrhea                  | • headache                    |

#### The most common side effects of Lynparza when used in combination with abiraterone and prednisone or prednisolone are:

- |                             |                                 |
|-----------------------------|---------------------------------|
| • low red blood cell counts | • low white blood cell counts   |
| • tiredness or weakness     | • dizziness                     |
| • diarrhea                  | • stomach-area (abdominal) pain |
| • loss of appetite          |                                 |

**Nausea or vomiting is common** during treatment with Lynparza. Tell your healthcare provider if you get nausea or vomiting. Your healthcare provider may prescribe medicines to treat these symptoms.

These are not all of the possible side effects of Lynparza.

Call your healthcare provider 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°F to 77°F (20°C to 25°C).
- Store Lynparza in the original bottle to protect it from moisture.

**Keep Lynparza and all medicines out of 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 that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about Lynparza that is written for health professionals

**What are the ingredients in Lynparza?**

**Active ingredient:** olaparib

**Inactive ingredients:**

Tablet contains: copovidone, mannitol, colloidal silicon dioxide and sodium stearyl fumarate

Tablet coating contains: hypromellose, polyethylene glycol 400, titanium dioxide, ferric oxide yellow and ferrosoferric oxide (150 mg tablet only)

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For more information, call 1-800-236-9933 or go to [www.Lynparza.com](http://www.Lynparza.com).

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