

Lynparza (Lin Par Zuh) tablets

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

prostate cancer with certain inherited or acquired abnormal genes called homologous recombination repair (HRR genes). Lynparza is used when the cancer has spread to other parts of the body (metastatic), and no longer responds to a medical or surgical treatment that lowers testosterone, and has progressed after treatment with enzalutamide or abiraterone. Your healthcare provider will perform a test to make sure Lynparza is right for you.

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

- have lung or breathing problems
- have kidney problems
- Males with female partners who are pregnant or able to become pregnant should use effective birth control (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 final dose.

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.

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.

How should I take Lynparza?

- Take Lynparza tablets exactly as your healthcare provider tells you.
- Do not change your dose or stop taking Lynparza unless your healthcare provider tells you to. Your healthcare provider may temporarily stop treatment with Lynparza or change your dose of Lynparza if you experience side effects.
- Your healthcare provider will decide how long you stay on treatment.
- Do not take more than 4 Lynparza tablets in 1 day. If you have any questions about Lynparza, please talk to your healthcare provider or pharmacist.
- Take Lynparza by mouth 2 times a day.
- Each dose should be taken about 12 hours apart.
- Swallow Lynparza tablets whole. Do not chew, crush, dissolve, or divide the tablets.
- Take Lynparza with or without food.
- 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 lower the amount of testosterone in your body (surgical castration).
- 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

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.

If you have any unused Lynparza, do not throw it in the trash and do not flush it down the sink or toilet. Dispose of unused medicines through community take-back disposal programs when available. If no community take-back disposal program is available go to www.fda.gov/drugdisposal for information on how to dispose of medication the right way.

Lynparza may cause serious side effects, including:

Bone marrow problems called Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML). Some people who have ovarian cancer or breast cancer and 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. 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
- shortness of breath
- frequent infections
- blood in urine or stool
- fever
- bruising or bleeding more easily
- weight loss
- feeling very tired

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 or completely stop treatment if you develop pneumonitis. Pneumonitis may lead to death. Blood clots (Venous Thromboembolic Events). Some people with prostate cancer who take Lynparza along with gonadotropinreleasing hormone (GnRH) analog therapy may develop a blood clot in a deep vein, usually in the leg (venous thrombosis) or a clot in the lung (pulmonary embolism). Tell your healthcare provider 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.

What are the possible side effects of Lynparza?

The most common side effects of Lynparza are:

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

These are not all the possible side effects of Lynparza. Call your healthcare provider for medical advice about side effects.

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