PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

Lynparza® 100 mg

Film-coated tablets

Composition:

Each tablet contains:

Olaparib 100 mg

Lynparza® 150 mg

Film-coated tablets

Composition:

Each tablet contains:

Olaparib 150 mg

For inactive ingredients, please see section 6 – "Further Information".

Please see also section 2 – "Important information regarding some of the medicine's ingredients".

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Lynparza is intended for:

Ovarian cancer:

Lynparza is indicated as monotherapy for the:

- Monotherapy, maintenance treatment of adult patients with advanced BRCA1/2-mutated (germline or somatic) high-grade epithelial ovarian (or fallopian tube or primary peritoneal) cancer who are in response (complete or partial) to first-line platinum-based chemotherapy.
- Maintenance treatment of patients with platinum-sensitive relapsed high-grade epithelial ovarian (or fallopian tube, or primary peritoneal) cancer who are in response (complete response or partial response) to platinum-based chemotherapy.

First-line Maintenance Treatment of Advanced Ovarian Cancer in Combination with Bevacizumab:

- For the maintenance treatment, in combination with bevacizumab, of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability

Breast cancer:

Germline BRCA-mutated HER2-negative Metastatic Breast Cancer:

- For the treatment of metastatic breast cancer in patients with mutations in BRCA and HER2-negative, who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting.

Adjuvant Treatment of Germline BRCA-mutated HER2-negative High Risk Early Breast Cancer:

- For the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy.

Adenocarcinoma of the pancreas:

First-line Maintenance Treatment of Germline BRCA-mutated Metastatic Pancreatic Adenocarcinoma:

- For the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma

whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

Prostate cancer:

- For the treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA1/2 or ATM- mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone.
- In combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious HRR-mutated (HRRm) metastatic castration-resistant prostate cancer (mCRPC).

If you have hormone receptor (HR)-positive disease, the recommendations are treatment with endocrine therapy. Your doctor will perform a test to make sure that Lynparza is right for you.

Lynparza contains the active substance olaparib. Olaparib is a type of cancer medicine called a PARP inhibitor. PARP inhibitors can trigger the death of cancer cells by blocking an enzyme that helps repair DNA.

When Lynparza is used in combination with abiraterone (an androgen receptor signaling inhibitor), the combination may help enhance anti-cancer effect in prostate cancer cells with or without faulty DNA repair genes (e.g., BRCA genes).

Therapeutic group

PARP (poly [adenosine diphosphate-ribose] polymerase) inhibitor.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient olaparib or to any of the other ingredients of this medicine (see section 6 – “Further Information”).
- You are breast-feeding (for additional information, please see section 2 below).

Do not take Lynparza if any of the conditions listed above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before taking Lynparza.

Special warnings regarding use of Lynparza:

Before or during the course of treatment with Lynparza, tell the doctor if:

- you have low blood-cell counts. These may be low red blood-cell count (anaemia), low white blood-cell count (neutropaenia), or low platelet count (thrombocytopenia).
  For further information, see section 4 – “Side Effects”, including the signs and symptoms you need to pay attention to (such as: fever or infection, bruising or bleeding). In a small number of patients, these may be a sign of a more serious problem with the bone marrow such as ‘myelodysplastic syndrome’ (MDS) or ‘acute myeloid leukaemia’ (AML).
- you experience any new or worsening symptoms of shortness of breath, coughing, or wheezing. A small number of patients treated with Lynparza reported inflammation of the lungs (pneumonitis). Pneumonitis is a serious condition that can often require hospital treatment.
- you experience any new or worsening symptoms of pain or swelling in an extremity, shortness of breath, chest pain, breathing that is more rapid than normal, or heart beats faster than normal. A small number of patients treated with Lynparza were reported to develop a blood clot in a deep vein, usually in the leg (venous thrombosis), or a clot in the lungs (pulmonary embolism).
- you notice yellowing of your skin or the whites of your eyes, abnormally dark urine (brown coloured), pain on the right side of your stomach area (abdomen), tiredness, feeling less hungry than usual or unexplained nausea and vomiting, contact your doctor immediately as this may indicate problems with your liver.

If you think any of these may apply to you, talk to your doctor, pharmacist or nurse before or during treatment with Lynparza.

Tests and checks

Your doctor will refer you for blood tests before and during treatment with Lynparza.

You will perform blood tests in the following manner:

- before treatment
- every month for the first year of treatment
- at regular intervals decided by your doctor after the first year of treatment.

If your blood count falls too low, it may be necessary to have a blood transfusion (where you are given new blood or blood-based products from a donor).

Drug interactions

If you are taking, or have recently taken, or about to take, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, because Lynparza can affect the way some other medicines work and also other medicines can affect the way Lynparza works, **especially if you are taking:**

- any other anticancer medicines.
- a vaccine or a medicine that suppresses the immune system, as you may need to be closely monitored.
- itraconazole, fluconazole - used to treat fungal infections.
- telithromycin, clarithromycin and erythromycin - used to treat bacterial infections.
- protease inhibitors boosted with ritonavir or cobicistat, boceprevir, telaprevir, nevirapine, efavirenz - used to treat viral infections, including HIV.
- rifampicin, rifapentine, rifabutin - used for bacterial infections, including tuberculosis (TB).
- phenytoin, carbamazepine, phenobarbital - used as a sedative or to treat fits (seizures) and epilepsy.
- herbal remedies containing St. John's Wort (*Hypericum perforatum*) - used mainly to treat depression.

- digoxin, diltiazem, furosemide, verapamil, valsartan - used to treat heart conditions or high blood pressure.
- bosentan - used to treat pulmonary artery hypertension.
- statins, for example simvastatin, pravastatin, rosuvastatin - used to lower blood cholesterol levels.
- dabigatran – used to thin the blood.
- 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 health problems.
- cisapride - used to treat stomach problems.
- colchicine – used to treat gout.
- cyclosporine, sirolimus, tacrolimus - used to suppress the immune system.
- methotrexate - used to treat cancer, rheumatoid arthritis and psoriasis.
- gonadotropin-releasing hormone (GnRH) analog therapy in addition to Lynparza for prostate cancer - 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 are taking Lynparza for early breast cancer and you have hormone receptor-positive disease, you should continue to take hormonal therapy during your treatment with Lynparza.

Tell your doctor, pharmacist or nurse if you are taking any of the above or any other medicines. The medicines listed here may not be the only ones that could affect Lynparza.

Use of the medicine and food

Do not drink grapefruit juice while you are being treated with Lynparza. Grapefruit can affect the way Lynparza works.

Pregnancy, breast-feeding and fertility

Women:

- You should not take Lynparza if you are pregnant or might become pregnant, because Lynparza may harm an unborn baby.

- You should avoid becoming pregnant while taking Lynparza. If you are having sex, you should use two effective methods of contraception while taking Lynparza and for 6 months after taking the last dose. It is not known whether Lynparza affects the effectiveness of some hormonal contraceptives. Please tell your doctor if you are taking a hormonal contraceptive, as your doctor may add a non-hormonal contraceptive method.
- You should have a pregnancy test before starting Lynparza, at regular times during treatment and 6 months after taking the last dose of Lynparza. If you become pregnant during this time, you must talk to your doctor straight away.
- It is not known whether Lynparza passes into breast milk. Do not breast-feed if you are taking Lynparza and for 1 month after taking the last dose of Lynparza. If you are planning to breast-feed, tell your doctor.

Men:

- You must use a condom when having sex with a female partner, even if she is pregnant, while taking Lynparza and for 3 months after taking the last dose of Lynparza. It is not known whether Lynparza passes into semen.
- Your female partner must also use a suitable method of contraception.
- You must not donate sperm during treatment and for 3 months after taking the last dose.

Driving and using machines

Lynparza may influence your ability to drive and use machines. If you feel dizzy, weak, or tired while taking Lynparza, do not drive or use tools or machines.

Important information regarding some of the medicine's ingredients

This medicine contains less than 1 mmol sodium (23 mg) per 100 mg or 150 mg tablet, that is to say essentially "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Your doctor has prescribed Lynparza **film-coated tablets** for you.

Always take Lynparza according to your doctor's instructions.

The dosage and manner of treatment will be determined by the doctor only.

Check with the doctor or pharmacist if you are uncertain about the dosage and manner of treatment with Lynparza.

Do not exceed the recommended dose.

How to take

- **Swallow Lynparza tablets whole, with or without food.**
- Take Lynparza once in the morning and once in the evening.
- Do not chew, crush, dissolve or divide the tablets as this may affect how quickly the medicine gets into your body.

Dosage

- **Your doctor will tell you how many tablets of Lynparza to take. It is important that you take the total recommended dose each day. Keep doing so for as long as your doctor, pharmacist or nurse tells you to.**
- **The usual recommended dose is 300 mg (2 x 150 mg tablets) twice a day - a total of 4 tablets each day.**

Your doctor may prescribe a different dose if:

- you have problems with your kidneys. You will be asked to take 200 mg (2 x 100 mg tablets) twice a day – a total of 4 tablets each day.
- you are taking certain medicines that may affect Lynparza (please see section 2).
- you have certain side effects while you are taking Lynparza (please see section 4). Your doctor may lower your Lynparza dose or stop treatment, either for a short time or permanently.

If you have accidentally taken a higher dose

If you took an overdose or if a child has accidentally swallowed the medicine, immediately refer to your doctor or to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take Lynparza

If you forget to take Lynparza at the scheduled time, do not take a double dose to make up for a forgotten dose. Take your next normal dose at its scheduled time and consult the doctor.

Adhere to the treatment regimen as recommended by your doctor.
Do not discontinue treatment with Lynparza without consulting your doctor.

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.
If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Lynparza may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Side effects that require special attention:
Tell your doctor straight away if you notice any of the following side effects:
Very common side effects (affect more than 1 in every 10 patients):

- feeling shortness of breath, feeling very tired, having pale skin, or fast heart beat - these may be symptoms of a low red blood cell count (anaemia).

Uncommon side effects (affect up to 1 in every 100 patients):

- allergic reactions (e.g., hives, difficulty breathing or swallowing, dizziness which are signs and symptoms of hypersensitivity reactions).
- itchy rash or swollen, reddened skin (dermatitis).
- serious problems with bone marrow (myelodysplastic syndrome (MDS) or acute myeloid leukaemia (AML)). Please see section 2 (may affect more than 1 in 100 people over their lifetime).
- inflammation of the lungs, which can cause coughing with a fever and difficulty breathing (pneumonitis).

Other side effects:
Very common side effects (affect more than 1 in every 10 patients):

- nausea
- vomiting
- feeling tired or weak
- indigestion or heartburn (dyspepsia)

- loss of appetite
- headache
- changes in the way food tastes
- feeling dizzy
- cough
- shortness of breath
- diarrhoea. If it gets severe, tell your doctor straight away.

Very common side effects that may show up in blood tests:

- low white blood cell count (leukopenia or neutropenia) which may decrease your ability to fight infection and may be associated with fever.

Common side effects (affect 1-10 in every 100 patients):

- rash
- sore mouth (stomatitis)
- pain in the stomach area under the ribs (upper abdominal pain).
- blood clot in a deep vein, usually in the leg (venous thrombosis) that may cause symptoms such as pain or swelling of the legs, or a clot in the lungs (pulmonary embolism) that may cause symptoms such as shortness of breath, chest pain, breathing that is more rapid than normal or heart beats faster than normal.

Common side effects that may show up in blood tests:

- low white blood cell count (lymphopenia) which may decrease your ability to fight infection and may be associated with fever.
- decrease in the number of platelets in blood (thrombocytopenia) - you may notice the following symptoms:
    - bruising or bleeding for longer than usual if you hurt yourself.
- increase in blood creatinine levels - this test is used to check how your kidneys are working.
- abnormal liver function tests.

Uncommon side effects that may show up in blood tests:

- increase in the size of red blood cells (not associated with any symptoms).

Rare side effects (may affect up to 1 in 1,000 patients):

- Facial swelling (angioedema).
- Painful inflammation of the fatty tissue under the skin (erythema nodosum).

Not known (cannot be estimated from available data)

- signs of liver problems, such as yellowing of your skin or the whites of your eyes (jaundice), nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (brown coloured), feeling less hungry than usual, tiredness.

Your doctor will test your blood every month for the first year of treatment and at regular intervals after that. Your doctor will tell you if there are any changes in your blood test that might need treatment.

If a side effect appears, if any of the side effects worsens, or when you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in the original package to protect from moisture.
- This medicine does not require any special temperature storage conditions. Storage at room temperature is recommended.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Copovidone K28, Mannitol, Hypromellose 2910, Silica, colloidal anhydrous, Sodium stearyl fumarate, Titanium dioxide, Macrogol 400, Iron oxide yellow

  In addition, Lynparza 150 mg contains:
  Iron oxide black

- **What the medicine looks like and the content of the package?**
  Lynparza 100 mg tablets are yellow to dark yellow, oval, bi-convex, film-coated tablets, marked with “OP100” on one side and plain on the other.
  Lynparza 150 mg tablets are green to green/grey, oval, bi-convex, film-coated tablets, marked with “OP150” on one side and plain on the other.
  Lynparza is supplied in packs containing 56 film-coated tablets (7 blisters of 8 tablets each), or multipacks containing 112 (2 packs of 56) film-coated tablets.
  Not all pack sizes may be marketed.

Manufacturer:
AstraZeneca UK limited, Silk Road, Business Park, Macclesfield, Cheshire SK10 2NA, UK

License Holder:
AstraZeneca (Israel) Ltd.,
1 Atirei Yeda St.,
Kfar Saba 4464301

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Lynparza 100 mg - 161-63-35469

Lynparza 150 mg - 161-64-35470

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