PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LYNPARZA 100 mg Film-coated tablets

LYNPARZA 150 mg Film-coated tablets

(Olaparib)

Read all of this leaflet carefully before you start taking LYNPARZA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LYNPARZA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LYNPARZA is and what it is used for
2. What you need to know before you take LYNPARZA
3. How to take LYNPARZA
4. Possible side effects
5. How to store LYNPARZA
6. Contents of the pack and other information

1. What LYNPARZA is and what it is used for

LYNPARZA tablets contain the active substance olaparib. Olaparib is a type of medicine called a PARP (poly [adenosine diphosphate-ribose] polymerase) inhibitor. PARP inhibitors can destroy cancer cells that are not good at repairing DNA damage. These specific cancer cells can be identified by response to platinum chemotherapy or by looking for faulty (mutated) DNA repair genes, such as *BRCA* (Breast Cancer) or HRR (Homologous Recombination Repair) genes.

- LYNPARZA is used for the treatment of a type of ovarian cancer (*BRCA*-mutated). It is used once the cancer has responded to treatment with standard platinum-based chemotherapy. A test is used to determine whether you have *BRCA*-mutated ovarian cancer.
- LYNPARZA is used for the treatment of ovarian cancer that has come back (recurred). LYNPARZA can be started once the cancer has responded to previous treatment with standard platinum-based chemotherapy.
- LYNPARZA is used in combination with another anti-cancer medicine called bevacizumab for the treatment of ovarian cancer. These medicines are used together once the cancer has responded to the first treatment with standard platinum-based chemotherapy and bevacizumab.
- LYNPARZA is used for the treatment of a type of breast cancer (*BRCA*-mutated, HER2-negative) when the cancer has not spread to other parts of the body, and you have previously received chemotherapy medicine treatment. A test is used to find out whether you have *BRCA*-mutated breast cancer.
- LYNPARZA is used for the treatment of a certain type of breast cancer (germline *BRCA*-mutated, human epidermal growth factor receptor 2-negative [HER2-negative]) which has spread beyond the original tumour. You should have received chemotherapy medicines either before or after your cancer has spread. A test is used to determine whether you have germline

  BRCA-mutated breast cancer.
- LYNPARZA is used for the treatment of a type of pancreatic cancer (germline *BRCA*-mutated) which has spread beyond the original tumour. It is used if the cancer has not progressed after treatment with chemotherapy. A test is used to determine whether you have germline *BRCA*-mutated pancreatic cancer.
- LYNPARZA is used for the treatment of a type of prostate cancer (HRR-mutated) which has spread beyond the original tumour and no longer responds to medical or surgical treatment that lowers testosterone. You should have already received certain hormonal treatments such as abiraterone acetate or enzalutamide. A test is used to determine whether you have this type of prostate cancer.

- LYNPARZA is used for the treatment of prostate cancer that has spread to other parts of the body (metastatic) beyond the original tumour and no longer responds to medical or surgical treatment that lowers testosterone. LYNPARZA is used in combination with another anti-cancer medicine called abiraterone, together with the steroid medicine, prednisone or prednisolone.

When LYNPARZA is given in combination with other anti-cancer medicines it is important that you also read the patient information leaflets of these other medicines. If you have any questions about these medicines, ask your doctor.

2. What you need to know before you take LYNPARZA

Do not take LYNPARZA:

- If you are hypersensitive (allergic) to olaparib or any of the other ingredients of LYNPARZA (listed in section 6).
- If you have severe kidney disease with increased blood creatinine levels.
- If you have severe liver disease (Child-Pugh class C).
- If you are pregnant or think you may be pregnant, and if you are breastfeeding. See the section below, “Pregnancy, breastfeeding and fertility” for more details.

Warnings and precautions

Take special care with LYNPARZA if:

- you have low blood cell counts on testing. These may be low red blood cell counts, low white blood cell counts, or low platelet counts. See section 4 for more information about these side effects, including the signs and symptoms you need to look out for (fever or infection, bruising or bleeding). These may be a sign of more serious problems 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. Some patients treated with LYNPARZA reported inflammation of the lungs (pneumonitis). Pneumonitis is a serious condition that can often require hospital treatment.

- you experience swelling, redness, and pain in legs, shortness of breath, chest pain or discomfort, rapid breathing or coughing up blood. Some patients treated with LYNPARZA reported pulmonary embolism (blood clots that blocks the flow of blood through the vein, usually in the leg, and travels to the lung. Pulmonary embolism is a serious condition that can often require hospital treatment.

If you think any of these may apply to you, talk to your doctor before you take LYNPARZA.

Other medicines and LYNPARZA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

You should not take LYNPARZA if you are taking any other anti-cancer agents.

Some medicines can affect the levels of LYNPARZA in your body. Also, LYNPARZA can affect the way some other medicines work. You should inform your doctor if you are taking medicines containing the following active substances:

- Itraconazole, fluconazole (used to treat fungal infections).
- Telithromycin, clarithromycin, erythromycin, ciprofloxacin, nafcillin (used to treat bacterial infections).
- Ritonavir, nelfinavir, indinavir, saquinavir, nevirapine, cobicistat, boceprevir, telaprevir, etravirine, efavirenz (used to treat viral infections, primarily HIV infection).
- Rifampicin, rifapentine, rifabutin (used to treat bacterial infections, primarily tuberculosis).
- Phenytoin, carbamazepine, phenobarbitone (used to treat seizures and epilepsy).
- St John’s Wort (a herbal remedy used mainly for depression).

- 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 (used to treat stomach problems).
- Ciclosporin, 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).

Tell your doctor or pharmacist if you take any of these or any other medicines. The medicines listed here may not be the only ones that could interact with LYNPARZA.

LYNPARZA with food, drink and alcohol

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

Pregnancy, breastfeeding and fertility

If you are pregnant, you should not take LYNPARZA. You should not become pregnant while taking LYNPARZA.

If you are pregnant or breastfeeding, think you may be pregnant or you are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking LYNPARZA.

Female patients: Talk to your doctor before taking LYNPARZA if you are pregnant, think you may be pregnant or you are planning to have a baby. This is because LYNPARZA may harm an unborn child.
If you are able to become pregnant, you must use two forms of effective contraception whilst taking LYNPARZA and for 6 months after receiving the last dose of LYNPARZA. If you do become pregnant during treatment, tell your doctor straight away.

Male patients: You must use a condom when having sexual intercourse with a female partner, whether your partner is pregnant or not pregnant, whilst you are taking LYNPARZA and for 3 months after receiving the last dose of LYNPARZA. Your female partner must also use a suitable method of contraception. You must not donate sperm whilst taking LYNPARZA and for 3 months after receiving the last dose of LYNPARZA.

Driving and using machines

LYNPARZA may affect your ability to drive or use machines. If you feel dizzy, weak, or tired while taking LYNPARZA, take special care when driving or using tools or machines.

3. How to take LYNPARZA

Do not share medicines prescribed for you with any other person.
Always take LYNPARZA exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

- The usual dose is two 150 mg tablets taken twice each day (a total of 4 tablets each day). Your doctor may prescribe a different dose if you have problems with your kidneys, or are taking certain medicines that may interact with LYNPARZA (see section 3) or if you experience certain side effects while you are taking LYNPARZA (see section 4). Your doctor will tell you how many tablets of LYNPARZA to take and it is important that you take the total recommended daily dose. Your doctor will decide how long you stay on treatment.

- Swallow LYNPARZA tablets whole. Do not chew, crush, dissolve or divide the tablets as this may affect how quickly the medicine gets into your body.
- Take LYNPARZA tablets at about the same time each morning and evening.
- LYNPARZA tablets may be taken with or without food.
- Do not drink grapefruit juice while you are being treated with LYNPARZA. It can affect the way LYNPARZA works.

If you have the impression that the effect of LYNPARZA is too strong or too weak, tell your doctor or pharmacist.

If you take more LYNPARZA than you should

If you take more than your normal dose, contact your doctor or the nearest hospital right away.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take LYNPARZA

If you forget to take LYNPARZA, take your next normal dose at its scheduled time. Do not take a double dose (two doses at the same time) to make up for forgotten tablets.

4. Possible side effects

LYNPARZA can have side effects.

Not all side effects reported for LYNPARZA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LYNPARZA, please consult your health care provider for advice.

If any of the following happens, stop using LYNPARZA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- feeling short of breath, feeling very tired, pale skin or fast heart beat - these may be

symptoms of a decrease in the number of red blood cells (anaemia).

- allergic reactions (e.g. hives, difficulty breathing or swallowing, dizziness which are signs and symptoms of hypersensitivity reactions).
- swelling, redness, and pain in legs, shortness of breath, chest pain or discomfort, rapid breathing or coughing up blood (which are symptoms of pulmonary embolism).

These are very serious side effects. If you have them, you may have had a serious reaction to LYNPARZA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- feeling sick (nausea)
- being sick (vomiting)
- feeling tired or weak
- indigestion or heartburn (dyspepsia)
- pain in the stomach area under the ribs (upper abdominal pain)
- loss of appetite
- headache
- changes in taste of foods (dysgeusia)
- feeling dizzy
- cough
- diarrhoea – if it gets severe, tell your doctor straight away.
- rash
- sore mouth (stomatitis)

Frequent side effects that may show up in blood tests:

- 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.
- low white blood cell count (leukopenia or neutropenia) which may decrease your ability to fight

infection and may be associated with fever.

- low white blood cell count (lymphopenia) which may decrease your ability to fight infection and may be associated with fever.
- increase in blood creatinine - this test is used to check how your kidneys are working.

Less frequent side effects:

- Itchy rash on swollen, reddened skin (dermatitis).
- Facial swelling (angioedema).
- Serious problems with bone marrow (myelodysplastic syndrome or acute myeloid leukaemia), see section 2.
- Painful inflammation in a part of the fatty layer of the skin (erythema nodosum).

Less frequent side effects that may show up in blood tests:

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

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 you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LYNPARZA.

5. How to store LYNPARZA

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package in order to protect from moisture.

Do not use after the expiry date stated on the bottle, blister and carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LYNPARZA contains

The active substance is olaparib.

The other ingredients are:

Tablet core: Copovidone, Colloidal silicon dioxide, Mannitol, Sodium stearyl fumarate.

Tablet coating: Hypromellose, Macrogol 400, Titanium dioxide (E171), Iron oxide yellow (E172), Iron oxide black (E172) (150 mg tablets only).

What LYNPARZA looks like and contents of the pack

LYNPARZA 100 mg tablet is a yellow to dark yellow, oval, bi-convex, film- coated tablet, marked with ‘OP100’ on one side and plain on the other side.

LYNPARZA 150 mg tablet is a green to green/grey oval, bi-convex, film-coated tablet, marked with ‘OP150’ on one side and plain on the other side.

LYNPARZA is supplied in:

- Blisters containing 56 film-coated tablets, packed in cartons containing 7 blisters of 8 tablets each, or 112 (2 x 56) film-coated tablets.
- HDPE bottles containing desiccant with a child resistant closure containing 60 or 120 tablets.

Not all package sizes may be marketed.

Holder of certificate of registration

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LYNPARZA 150: 52/26/0746

Access to corresponding Professional Information

For the latest Professional Information, kindly scan the QR code on the carton.

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