Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Zejula 100 mg
Hard capsules

Name and quantity of active ingredient:
Each capsule contains:
niraparib 100 mg

For a list of inactive ingredients and allergens in this medicine, see section 6 'Additional information'. See also section 2 under 'Important information about some of this medicine's ingredients'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

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

1. What is this medicine intended for?

What Zejula is used for?
Zejula is used as a single maintenance treatment in adult patients with:

- advanced high-grade epithelial ovarian cancer (FIGO Stages III and IV), cancer of the fallopian tubes, or primary peritoneal cancer after full or partial response to first-line platinum-based chemotherapy has been achieved.

- high-grade recurrent epithelial ovarian cancer that is sensitive to platinum, cancer of the fallopian tubes (part of the female reproductive system that connects the ovaries to the uterus), or primary peritoneal (the membrane lining the abdomen) cancer that has responded (fully or partially) to previous treatment with platinum-based chemotherapy.

What Zejula is and how it works?
Zejula contains the active substance niraparib. Niraparib is a type of anti-cancer medicine called a PARP inhibitor. PARP inhibitors block an enzyme called poly [adenosine diphosphate-ribose] polymerase (PARP). PARP helps cells repair damaged DNA so blocking it means that the DNA of cancer cells cannot be repaired. This results in death of tumor cells, which helps to control the cancer.

Therapeutic group: antineoplastics

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient niraparib or to any of the other ingredients in this medicine (see section 6 'Additional information')
- you are breastfeeding

Special warnings about using this medicine

Talk to your doctor before and while taking this medicine if any of the following applies to you:

Low blood-cell counts
Zejula lowers your blood-cell counts, red blood-cell count (anemia), white blood-cell count (neutropenia), or blood-platelet count (thrombocytopenia). Signs and symptoms you need to look out for include fever or infection, and abnormal bruising or bleeding (see section 4 for more information).

Myelodysplastic syndrome/acute myeloid leukemia
Rarely, low blood-cell counts may be a sign of more serious problems with the bone marrow such as 'myelodysplastic syndrome' (MDS) or 'acute myeloid leukemia' (AML).

High blood pressure
Zejula can cause high blood pressure, which in some cases could be severe. Your doctor may also give you medicine to treat high blood pressure and adjust your Zejula dose, if necessary. Your doctor may recommend that you monitor your blood pressure at home and advise you when to contact him in the event of a rise in your blood pressure.

Posterior reversible encephalopathy syndrome (PRES)
PRES, a rare neurological side effect, has been found to be associated with treatment with Zejula. If you experience a headache, changes in vision, confusion or a seizure with or without a rise in blood pressure, refer to your treating physician.

Children and adolescents
Do not give Zejula to children under 18 years old. This medicine has not been studied in this age group.

Tests and follow-up
- During the course of this treatment, your doctor will regularly refer you to a blood test.
- Your doctor may refer you to a bone marrow test to find out if you have myelodysplastic syndrome/acute myeloid leukemia.
- During the course of this treatment, your doctor will measure your blood pressure regularly.

Other medicines and Zejula
If you are taking or have recently taken, or might take other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy, breastfeeding, and fertility

Pregnancy
Do not take Zejula during pregnancy because it could harm your baby. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If you are a woman who could become pregnant you must use reliable contraception while you are taking Zejula, and you must continue to use reliable contraception for one month after taking your last dose. Your doctor may ask you to confirm that you are not pregnant by having a pregnancy test before starting your treatment. Contact your doctor straight away if you become pregnant while you are taking Zejula.

Breastfeeding
Do not take Zejula if you are breastfeeding because it is not known if it passes into breast milk. If you are breastfeeding, you must stop before you start taking Zejula and you must not begin breastfeeding again until one month after taking your last dose. Ask your doctor for advice before taking this medicine.

Driving and using machines
When you are taking Zejula it may make you feel weak, unfocused, tired or dizzy and therefore influence your ability to drive and use machines. Observe particular caution when driving or using machines.

Important information about some of this medicine's ingredients

Zejula contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Zejula contains tartrazine (E102)
It may cause allergic reactions.

3. How to use this medicine?
Always use this medicine according to your doctor's instructions. Always take this medicine exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.
For ovarian cancer that has responded to first treatment with platinum-based chemotherapy:
The usually recommended starting dose is 200 mg (two 100 mg capsules), taken together once a day, with or without food. If you weigh ≥ 77 kg and have platelet count ≥ 150,000/µL before starting treatment, the usually recommended starting dose is 300 mg (three 100 mg capsules), taken together once a day, with or without food.

For ovarian cancer that has come back (recurred):
The usually recommended starting dose is 300 mg (three 100 mg capsules), taken together once a day, with or without food.

Take Zejula at approximately the same time each day. Taking Zejula at bedtime may help you to manage nausea.

Swallow the capsules whole, with some water. Do not chew or crush the capsules. There is no information about opening capsules and releasing their content.

Your doctor may recommend a lower dose if you experience side effects (such as nausea, tiredness, abnormal bleeding/bruising, anemia).

Your doctor will check you regularly, and you will normally continue to take Zejula as long as you experience benefit, and do not suffer unacceptable side effects.

Do not exceed the recommended dose.

If you have accidentally taken a higher dose of Zejula
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take Zejula
Do not take an additional dose if you miss a dose or vomit after taking Zejula. Take your next dose at its scheduled time. Do not take a double dose to make up for a forgotten dose. Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor, pharmacist or nurse.

4. Side effects

Like with all medicines, using Zejula may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Tell your doctor straight away if you notice any of the following serious side effects you may need urgent medical treatment:

Very common side effects - may affect more than 1 in 10 users
- Bruising or bleeding for longer than usual if you hurt yourself - these may be signs of a low blood platelet count (thrombocytopenia).
- Being short of breath, feeling very tired, having pale skin, or fast heartbeat - these may be signs of a low red blood cell count (anemia).
- Fever or infection – a low white blood cell count (neutropenia) can increase your risk of infection. Signs may include fever, chills, feeling weak or confused, cough, pain or burning feeling when passing urine. Some infections can be serious and may lead to death.
- Reduction in the number of white cells in the blood (leukopenia)

Common side effects – may affect 1-10 in 100 users
- Allergic reaction (including severe allergic reaction that might be life-threatening). Signs include a raised and itchy rash (hives) and swelling – sometimes of the face or mouth (angioedema), causing difficulty breathing, and collapse or loss of consciousness.

Rare side effects – may affect 1-10 in 10,000 users
- a medical emergency caused by a sudden increase in blood pressure, that could lead to organ damage or can be life-threatening
- a medical emergency that could lead to organ damage or can be life-threatening which is caused by a brain condition with symptoms including seizures, headache, confusion, and changes in vision (Posterior Reversible Encephalopathy Syndrome [PRES])

Talk to your doctor if you get any other side effects. These can include:

Very common side effects - may affect more than 1 in 10 users
- nausea
- heartburn
- decreased number of white cells in the blood
- decreased number of platelets in the blood
- decreased number of red cells in the blood (anemia)
- feeling tired
- feeling weak
- constipation

- vomiting
- stomach pain
- inability to sleep
- headache
- decreased appetite
- runny or stuffy nose
- diarrhea
- shortness of breath
- joint pain
- back pain
- high blood pressure
- indigestion
- dizziness
- cough
- urinary tract infection
- palpitations (feeling like your heart is skipping beats or beating harder than usual)

Common side effects - may affect 1-10 in 100 users
- sunburn-like reactions following exposure to light
- swelling in the feet, ankles, legs, and/or hands
- low potassium levels in the blood
- inflammation or swelling of the air passages between the mouth and nose and the lungs, bronchitis
- abdominal bloating
- feeling of worry, nervousness, or unease
- feeling sadness, depressed
- nose bleed
- weight loss
- muscle pain
- Impaired concentration, understanding, memory and thinking (cognitive impairment)
- pink eye (conjunctivitis)
- fast heart beat which may cause dizziness, chest pain or breathlessness
- dry mouth
- inflammation of the mouth and/or digestive tract
- rash
- elevated blood tests
- abnormal blood tests
- abnormal taste in mouth

Uncommon side effects - may affect 1-10 in 1,000 users
- reduction in the number of red blood cells, white blood cells, and platelets
- confusion
- inflammation of the lungs, which may cause shortness of breath and difficulty breathing (noninfectious pneumonitis).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

By reporting side effects, you can help provide more information about the safety of using this medicine.

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) which is stated on the carton and blister tray. The expiry date refers to the last day of that month.

Storage conditions:

- Do not store above 25°C.
- Do not use this medicine if you notice any damage or signs of tampering on the pack.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Capsule content:
lactose monohydrate, magnesium stearate
Capsule shell:
titanium dioxide (E 171), gelatin, brilliant blue FCF (E 133), erythrosine (E 127), tartrazine (E 102)
Printing ink:
shellac (E904), propylene glycol (E1520), potassium hydroxide (E525), black iron oxide (E172), sodium hydroxide (E524), and povidone (E1201).

This medicine contains lactose and tartrazine - see section 2 ‘Additional information’.

What Zejula looks like and contents of the pack:

hard capsules with a white opaque body and a purple opaque cap. The white opaque capsule body is printed with ‘100 mg’ in black ink, and the purple capsule cap is printed with ‘Niraparib’ in white ink.

The hard capsules are packed in packs of:

- 84 hard capsules (4 blister trays of 21 capsules)
- 56 hard capsules (4 blister trays of 14 capsules)
- 28 hard capsules (2 blister trays of 14 capsules)

Not all pack sizes may be marketed.

Manufacturer’s name and address:

GlaxoSmithKline (Ireland) Limited

12 Riverwalk

Citywest Business Campus

Dublin 24 YK11

Ireland

Registration holder's name and address:
Medison Pharma Ltd., 10 Hashiloah St., POB 7090, Petah Tikva

Registration number of the medicine in the Ministry of Health's National Drug Registry:
162-60-35740

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