Package leaflet: Information for the patient

Zejula 100 mg hard capsules
niraparib

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zejula is and what it is used for

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 tumour cell death, helping to control the cancer.

What Zejula is used for
Zejula is used in adult women for the treatment of cancer of the ovary, the fallopian tubes (part of the female reproductive system that connects the ovaries to the uterus), or the peritoneum (the membrane lining the abdomen).

It is used after the cancer has:
- responded to the first treatment with platinum-based chemotherapy, or
- come back (recurred) after the cancer has responded to previous treatment with standard platinum-based chemotherapy.

2. What you need to know before you take Zejula

Do not take Zejula
- if you are allergic to niraparib or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding.

Warnings and precautions
Talk to your doctor, pharmacist or nurse <u>before or while</u> taking this medicine if any of the following could apply to you:

Low blood-cell counts
Zejula lowers your blood-cell counts, such as your red blood-cell count (anaemia), 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). Your doctor will test your blood regularly throughout your treatment.

Myelodysplastic syndrome/acute myeloid leukaemia
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 leukaemia' (AML). Your doctor may want to test your bone marrow to check for these problems.

High blood pressure
Zejula can cause high blood pressure, which in some cases, could be severe. Your doctor will measure your blood pressure regularly throughout your treatment. He or she may also give you medicine to treat high blood pressure and adjust your Zejula dose, if necessary. Your doctor may advise home blood pressure monitoring and instruction on when to contact him or her in case of a rise in blood pressure.

Posterior Reversible Encephalopathy Syndrome (PRES)
A rare neurological side effect named Posterior Reversible Encephalopathy Syndrome (PRES) has been associated with Zejula treatment. If you have headache, vision changes, confusion or seizure with or without high blood pressure, please contact your doctor.

Children and adolescents
Children under 18 years of age should not be given Zejula. This medicine has not been studied in this age group.

Other medicines and Zejula
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy
Zejula should not be taken during pregnancy as 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 1 month after taking your last dose. Your doctor will ask you to confirm that you are not pregnant with a pregnancy test before starting your treatment. Contact your doctor straightaway if you become pregnant while you are taking Zejula.

Breast-feeding
Zejula should not be taken if you are breast-feeding as it is not known if it passes into breast milk. If you are breast-feeding, you must stop before you start taking Zejula and you must not begin breast-feeding again until 1 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, tired or dizzy and therefore influence your ability to drive and use machines. Observe caution when driving or using machines.

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 (E 102)
It may cause allergic reactions.

3. How to take Zejula

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For ovarian cancer that has responded to the first treatment with platinum-based chemotherapy
The recommended starting dose 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 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 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.

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

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

If you take more Zejula than you should
If you take more than your normal dose, contact your doctor immediately.

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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Very common (may affect more than 1 in 10 people)
- 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 (anaemia).
- Fever or infection – low white blood cell count (neutropenia) can increase your risk for 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 (may affect up to 1 in 10 people)

- Allergic reaction (including severe allergic reaction that can be life-threatening). Signs include raised and itchy rash (hives) and swelling—sometimes of the face or mouth (angioedema), causing difficulty in breathing, and collapse or loss of consciousness.

Rare (may affect up to 1 in 1000 people)

- A sudden increase in blood pressure, which may be a medical emergency that could lead to organ damage or can be life-threatening.
- A brain condition with symptoms including seizures (fits), headache, confusion, and changes in vision (Posterior Reversible Encephalopathy Syndrome or PRES), which is a medical emergency that could lead to organ damage or can be life-threatening.

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

Very common (may affect more than 1 in 10 people)

- Feeling sick (nausea)
- Heartburn (dyspepsia)
- Decreased number of white cells in the blood
- Decreased number of platelets in the blood
- Decreased number of red cells in the blood (anaemia)
- Feeling tired
- Feeling of weakness
- Constipation
- Vomiting
- Stomach pain
- Inability to sleep
- Headache
- Decreased appetite
- Runny or stuffy nose
- Diarrhoea
- Shortness of breath
- Back pain
- Joint pain
- High blood pressure
- Indigestion
- Dizziness
- Cough
- Urinary tract infection
- Palpitations (feeling like your heart is skipping beats or beating harder than usual)

Common (may affect up to 1 in 10 people)

- 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
- Feelings of sadness, depressed
- Nose bleed
- Decrease in weight
- Muscle pain
- Pink eye
- Fast heart beat 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 (may affect up to 1 in 100 people)
- Reduction in the number of red blood cells, white blood cells and platelets
- Confusional state
- Inflammation of the lungs which can cause shortness of breath and difficulty breathing (non-infectious pneumonitis)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zejula

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Do not use this medicine if you notice any damage or signs of tampering to 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. Contents of the pack and other information

What Zejula contains

- The active substance is niraparib. Each hard capsule contains niraparib tosylate monohydrate equivalent to 100 mg niraparib.

- The other ingredients (excipients) are:
  capsule content: magnesium stearate, lactose monohydrate
  capsule shell: titanium dioxide (E 171), gelatin, brilliant blue FCF (E 133), erythrosine (E 127), tartrazine (E 102)
  printing ink: shellac (E 904), propylene glycol (E 1520), potassium hydroxide (E 525), black iron oxide (E 172), sodium hydroxide (E 524), povidone (E 1201), and titanium dioxide (E 171).

This medicine contains lactose and tartrazine - see section 2 for more information.

What Zejula looks like and contents of the pack

Zejula hard capsules have 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 capsules contain a white to off-white powder.

The hard capsules are packed in blister packs of

- 84 × 1 hard capsules
- 56 × 1 hard capsules
- 28 × 1 hard capsules

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