▼ **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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.**

Zejula

niraparib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zejula.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your doctor or pharmacist to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from https://www.ebs.tga.gov.au/.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Zejula is used for

Zejula is used in adults 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 for the treatment of cancer that has:

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

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.

Ask your doctor if you have any questions about why it has been prescribed for you.
Your doctor may have prescribed it for another purpose.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take Zejula

When you must not take it

Do not take Zejula if you have an allergy to:

- niraparib or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include:

- skin rash,
- itching,
- shortness of breath or
- swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not take Zejula if you are breastfeeding.
It is not known if Zejula passes into breast milk. If you are breastfeeding, you must stop before you start taking Zejula and you must not beginbreast-feeding until 1 month after taking your last dose.

Do not take this medicine if you are pregnant or intend to become pregnant.
Zejula can harm your unborn baby and may cause loss of pregnancy (miscarriage).

If you are a woman who could become pregnant you must use highly effective contraception while you are taking Zejula, and you must continue to use reliable contraception for 6 months after taking your last dose.

If you are able to become pregnant, your doctor may perform a pregnancy test before you start treatment with Zejula.

Contact your doctor straightaway if you become pregnant while you are taking Zejula.

Do not take it after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor or pharmacist if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- **low blood counts**
  Zejula lowers your blood-cell counts, such as your red blood-cell count (anaemia), white blood-cell count (neutropaenia), or blood-platelet count (thrombocytopaenia). Signs and symptoms you need to look out for include fever or infection, and abnormal bruising or bleeding.
  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.
- **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.

Tell your doctor if you are pregnant or intend to become pregnant. Zejula can harm your unborn baby and may cause loss of pregnancy (miscarriage). See 'When you must not take it'.

If you have not told your doctor about any of the above, tell them before you start taking Zejula.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines and Zejula may interfere with each other. These include:

- medicines used to prevent rejection after an organ transplant, such as cyclosporin and tacrolimus
- alfentanil, a medicine used to manage pain
- ergotamine, a medicine to treat migraine
- medicines used to treat mental disorders such as pimozide, quetiapine and clozapine
- halofantrine, a medicine to treat malaria
- theophylline, a medicine to treat asthma
- ropinirole, a medicine to treat Parkinson's disease
- irinotecan, a medicine to treat cancer
- medicines to treat high cholesterol such as rosuvastatin, simvastatin and atorvastatin
- methotrexate, a medicine used to treat cancer, rheumatoid arthritis or psoriasis
- metformin, a medicine used to treat diabetes

These medicines may be affected by Zejula or may affect how well it works. You may need to use different amounts of your medicine or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Zejula.

How to take Zejula

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

Do not change the Zejula dose without talking to your doctor.

How much to take

The recommended starting dose is 2 capsules taken together once a day (total daily dose of 200 mg). For some patients, a starting dose of 300 mg (3 capsules) may be appropriate and recommended by your doctor based on clinical assessment.

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

How to take it

Swallow Zejula whole with a glass of water. Do not open, chew or crush the capsules.

When to take it

Take Zejula at approximately the same time each day.

Taking Zejula at bedtime may help you to manage nausea.

It does not matter if you take this medicine with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you. 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 forget to take it

If you forget to take Zejula, take your next dose at its scheduled time. Do not take an additional dose if you miss a dose or vomit after taking Zejula.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your doctor or pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Zejula. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

While you are taking Zejula

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Zejula.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while you are taking this medicine, tell your doctor immediately.

If you are a woman who could become pregnant you must use highly effective contraception while you are taking Zejula, and you must continue to use reliable contraception for 6 months after taking your last dose.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects. Your doctor will test your blood weekly for the first month, then monthly for 10 months and afterwards periodically.

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking Zejula or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen. Your doctor may interrupt your treatment or reduce your dose if you are having unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how Zejula affects you. This medicine may cause dizziness, tiredness, difficulty concentrating or weakness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Zejula.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor straight away if you notice any of the following:

- Feeling tired
- Feeling of weakness
- Feeling sick
- Stomach pain
- Vomiting
- Constipation
- Diarrhoea
- Indigestion
- Decreased appetite
- Inability to sleep
- Headache
- Dizziness
- Runny or stuffy nose
- Shortness of breath
- Cough
- High blood pressure
- Urinary tract infection
- Palpitations (feeling like your heart is skipping beats or beating harder than usual)
- Back pain
- Pain in joints

The above list includes the very common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor immediately if you notice any of the following serious side effects:

- Bruising or bleeding for longer than usual if you hurt yourself - these may be signs of a low blood platelet count (thrombocytopaenia).
- 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 – these may be signs of a low white blood cell count (neutropenia). Decrease in white blood cell count may decrease your ability to fight infections.
- Low blood cell counts due to a problem in the bone marrow or blood cancer starting from the bone marrow (MDS or AML)
- Allergic reaction (hypersensitivity, including anaphylaxis).
- Life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) (anaphylaxis)

Some serious side effects may only become known through tests.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.
Other side effects not listed above may occur in some people.

After taking Zejula

Storage

Keep your capsules in the pack until it is time to take them. If you take the capsules out of the pack they may not keep well.

Keep the medicine in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.
Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Zejula (niraparib 100 mg) capsule has a white body with “100 mg” printed in black ink and purple cap with “Niraparib” printed in white ink.

Zejula is available in packs of 56 and 84 capsules.

Ingredients

Zejula contains 100 mg of niraparib (as niraparib tosilate monohydrate) as the active ingredient:

It also contains

Capsule content:

- lactose monohydrate, magnesium stearate

Capsule shell:

- titanium dioxide, gelatin, brilliant blue FCF, erythrosine, tartrazine

Printing ink:

- Black Ink; SW-9040 (PI:12418).
- White Ink; TekPrint SB-0007P White Ink (PI 2216).

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.

Supplier

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