

ZEJULA Capsules

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using ZEJULA?

ZEJULA contains the active ingredient niraparib. ZEJULA is used as a treatment for ovarian, fallopian tube or peritoneal cancer that has completely or partially responded to treatment with platinum-based chemotherapy.

For more information, see Section [1. Why am I using Zejula?](#) in the full CMI.

2. What should I know before I use ZEJULA?

Do not use ZEJULA if you have ever had an allergic reaction to any medicine containing niraparib, lactose or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Zejula?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZEJULA and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ZEJULA?

Follow dosage directions given to you by your doctor or pharmacist and continue taking it for as long as your doctor tells you. More instructions can be found in Section [4. How do I use Zejula?](#) in the full CMI.

5. What should I know while using ZEJULA?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using ZEJULA.Tell your doctor if you have low blood counts, high blood pressure, myelodysplastic syndrome (MDS)/ acute myeloid leukaemia (AML), or posterior reversible encephalopathy syndrome (PRES).If you become pregnant while taking ZEJULA, tell your doctor immediately.If you could become pregnant you must use reliable contraception while you are taking ZEJULA, and 6 month after taking your last dose.Keep all your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine suddenly or change the dosage without checking with your doctor.Do not take this medicine if you are pregnant, intend to become pregnant or are breastfeeding.Do not begin breast-feeding until 1 month after taking your last dose.
Driving or using machines	<ul style="list-style-type: none">ZEJULA may cause dizziness, tiredness or weakness. If you have any of these symptoms, do not drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">Keep ZEJULA capsules in the pack, in a cool, dry place where the temperature stays below 25°C.Keep ZEJULA where children cannot reach it.

For more information, see Section [5. What should I know while using Zejula?](#) in the full CMI.

6. Are there any side effects?

The following common side effects may occur when taking ZEJULA: tiredness, weakness, nausea, 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, heart palpitations, back pain and joint pain. If you experience bruising and bleeding for longer than usual, fever or infection, or shortness of breath alongside tiredness, pale skin and a fast heartbeat or a life-threatening allergic reaction then contact your doctor immediately. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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 Capsules

Active ingredient(s): *Niraparib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZEJULA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZEJULA.**

Where to find information in this leaflet:

- [1. Why am I using Zejula?](#)
- [2. What should I know before I use Zejula?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Zejula?](#)
- [5. What should I know while using Zejula?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ZEJULA?

ZEJULA contains the active ingredient 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.

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

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.

2. What should I know before I use ZEJULA?

Warnings

Always check the ingredients to make sure you can use this medicine.

Do not use ZEJULA if:

- you are allergic 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.

- you are pregnant, intend to become pregnant or are breastfeeding.

Check with your doctor if you:

- have any other medical conditions including low blood counts, high blood pressure, myelodysplastic syndrome (MDS)/acute myeloid leukaemia (AML) or posterior reversible encephalopathy syndrome (PRES).
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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 begin breast-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.

Medical Conditions

Tell your doctor or pharmacist 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 (thrombocytopenia). 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 (MDS)/acute myeloid leukaemia (AML)

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.

3. What if I am taking other medicines?

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

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZEJULA

4. How do I use 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.

Follow the instructions provided and use ZEJULA until your doctor tells you to stop.

When to take ZEJULA

Take ZEJULA at approximately the same time each day.

Taking ZEJULA at bedtime may help you to manage nausea.

How to take ZEJULA

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

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

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 until disease progression, and as long as you do not suffer unacceptable side effects.

If you forget to take ZEJULA

ZEJULA should be used regularly at the same time each day. **If you miss your dose at the usual time, 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 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 are having trouble remembering when to take your medicine, ask your doctor or pharmacist for hints.

If you use too much ZEJULA

If you think that you have used too much ZEJULA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ZEJULA?

Things you should do

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

Call your doctor straight away if you:

- Become pregnant while taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using ZEJULA.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZEJULA affects you.

ZEJULA 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.

Looking after your medicine

- 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 ZEJULA in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>General disorders:</p> <ul style="list-style-type: none"> • Feeling tired • Feeling of weakness <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • Feeling sick • Stomach pain • Indigestion • Constipation • Vomiting • Diarrhoea <p>Respiratory disorders:</p> <ul style="list-style-type: none"> • Runny or stuffy nose • Shortness of breath • Cough <p>Metabolism and nutrition:</p> <ul style="list-style-type: none"> • Decreased appetite <p>Nervous system and psychiatric disorders</p> <ul style="list-style-type: none"> • Headache • Dizziness • Inability to sleep <p>Cardiac and vascular disorders:</p> <ul style="list-style-type: none"> • Palpitations (feeling like your heart is skipping beats or beating harder than usual) • High blood pressure <p>Musculoskeletal and connective tissues disorders:</p> <ul style="list-style-type: none"> • Back pain • Pain in joints <p>Infections:</p> <ul style="list-style-type: none"> • Urinary tract infection 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Blood Related:</p> <ul style="list-style-type: none"> • 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 – these may be signs of a low white blood cell count (neutropenia). • Low blood cell counts due to a problem in the bone marrow or blood cancer starting from the bone marrow (MDS or AML) <p>Kidney problems:</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • Lack of energy (fatigue), lack of strength (weakness) • Feeling sick (nausea), being sick (vomiting) • Loss of appetite • Changes in urination frequency and amount • Swelling in the legs, ankles or feet <p>Allergy Related</p> <ul style="list-style-type: none"> • Allergic reaction (hypersensitivity, including anaphylaxis). • Life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) (anaphylaxis) <p>Some other serious side effects may only become known through tests</p>	

What ZEJULA 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 (AUST R 305254)

Who distributes ZEJULA

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ZEJULA contains

Active ingredient (main ingredient)	Niraparib (as niraparib tosilate monohydrate)
Other ingredients (inactive ingredients)	<p>Capsule content:</p> <ul style="list-style-type: none"> • Lactose monohydrate • Magnesium stearate <p>Capsule shell:</p> <ul style="list-style-type: none"> • titanium dioxide • gelatin • brilliant blue FCF • erythrosine • tartrazine (E102) <p>Printing ink:</p> <ul style="list-style-type: none"> • Black Ink; SW-9040 (PI:12418). • White Ink; TekPrint SB-0007P White Ink (PI 2216).

Do not take this medicine if you are allergic to any of these ingredients.