

ZEJULA tablets

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.

1. Why am I taking ZEJULA?

ZEJULA tablets contain the active ingredient niraparib. 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).

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

2. What should I know before I take ZEJULA?

Do not use if you have ever had an allergic reaction to niraparib or any of the ingredients listed at the end of the CMI. Do not take ZEJULA if you are pregnant, intend to become pregnant or are breastfeeding.

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section [2. What should I know before I take 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 take ZEJULA?

- Follow the dosage instructions given to you by your doctor or pharmacist.

More instructions can be found in Section [4. How do I take ZEJULA?](#) in the full CMI.

5. What should I know while taking ZEJULA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking ZEJULA.• Keep all of your doctor's appointments so that your progress can be checked.• 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).• Tell your doctor immediately if you become pregnant whilst taking ZEJULA.• If you could become pregnant you must use reliable contraception whilst you are taking ZEJULA and for 6 months after your last dose.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or lower the dose without first checking with your doctor.• Do not take this medicine if you are pregnant, intend to become pregnant or are breastfeeding.• Do not begin breastfeeding until 1 month after taking your last dose.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how ZEJULA affects you.• ZEJULA may cause weakness, tiredness, dizziness or a lack of concentration in some people.
Looking after your medicine	<ul style="list-style-type: none">• Store ZEJULA tablets in the carton below 30°C

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

6. Are there any side effects?

Side effects which have been reported include feeling tired, feelings of weakness, feeling sick (nausea), stomach pain, vomiting, constipation, diarrhoea, indigestion, a decreased appetite, a change in the taste of food, an inability to sleep (insomnia), headache, dizziness, a runny or stuffy nose, shortness of breath, cough, urinary tract infection, back pain, joint pain.

If you experience an allergic reaction (symptoms include wheezing, difficulty in breathing, swelling of the lips/mouth/tongue, hay fever, lumpy rash ("hives") and fainting) go to the Emergency Department of your nearest hospital 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.

ZEJULA tablets

Active ingredient(s): *niraparib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZEJULA tablets. **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 taking Zejula?](#)
- [2. What should I know before I take Zejula?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Zejula?](#)
- [5. What should I know while taking Zejula?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking ZEJULA?

ZEJULA tablets contain 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

2. What should I know before I take ZEJULA?

Warnings

Do not take ZEJULA if:

- you are allergic to niraparib, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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 whilst taking ZEJULA and you must continue to use highly effective contraception for 6 months after taking your last dose.

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

Contact your doctor immediately if you become pregnant whilst taking ZEJULA.

- you are breastfeeding. It is not known if ZEJULA passes into breastmilk. If you are breastfeeding, you must stop before you start taking ZEJULA and you must not begin breastfeeding until 1 month after taking your last dose.

Check with your doctor if you:

- have any other medical conditions.
- have 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 to look out for include fever or infection and abnormal bruising or bleeding. Your doctor will complete blood tests regularly throughout your treatment.
- have myelodysplastic syndrome/acute myeloid leukemia**
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).
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. They may also give you medicine to treat high blood pressure and may also adjust your ZEJULA dose.
- posterior reversible encephalopathy syndrome (PRES)**
This is a rare neurological side effect which has been associated with ZEJULA treatment. If you have a headache, vision changes, confusion or a seizure either with or without high blood pressure contact your doctor.
- 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?](#)

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 may interfere with ZEJULA and affect how it works.

- medicines used to prevent rejection after an organ transplant, such as ciclosporin 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

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 take ZEJULA?

How much to take

- The recommended starting dose is 2 tablets taken together once a day (total daily dose of 200 mg).
- For some patients, a starting dose of 300 mg (3 tablets) may be appropriate and recommended by your doctor based on clinical assessment.
- If you experience side effects (such as nausea, tiredness, abnormal bruising/bleeding, anaemia) your doctor may recommend a lower dose.

When to take ZEJULA

- Take ZEJULA at the same time each day.
- Taking it at bedtime may help to manage nausea.

How to take it

- Swallow ZEJULA tablets whole with a glass of water.
- It does not matter if you take this medicine before or after food.

How long to take it

- Continue taking ZEJULA for as long as your doctor tells you to. 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 forget to take ZEJULA, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much ZEJULA

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

You should immediately:

- phone the Poisons Information Centre (**by calling 0800 POISON or 0800 764 766**), 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 taking 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.
- 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 the next 10 months and afterwards periodically.
- If you are a woman who could become pregnant you must use highly effective contraception whilst you are taking ZEJULA and continue to use effective contraception for 6 months after taking your last dose.

Call your doctor straight away if you:

- become pregnant whilst taking this medicine

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

Things you should not do

- Do not stop using this medicine suddenly 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.
- 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.

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 weakness, tiredness, dizziness or a lack of concentration in some people.

Looking after your medicine

- Store below 30°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 window sills.

Keep it where young children cannot reach it.

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
<ul style="list-style-type: none"> • feeling tired • feeling of weakness • feeling sick (nausea) • stomach pain • vomiting • constipation • diarrhoea • indigestion • decreased appetite • change in the taste of food (only if it worries you) • inability to sleep (insomnia) • headache • dizziness • a runny or stuffy nose • shortness of breath • cough • urinary tract infection • back pain • joint pain 	<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
<ul style="list-style-type: none"> • feeling like your heart is skipping beats or is beating harder than usual (palpitations) • hypersensitivity including anaphylaxis which may involve difficulty breathing - these may be signs of an allergic reaction • bruising or bleeding for longer than usual if you hurt yourself - these may be signs of a low blood platelet count (thrombocytopenia) • shortness of breath, feeling very tired, having paler skin than usual or a 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). A decrease in white blood cell count may decrease your ability to fight infections • severe infection associated with low blood pressure and possible organ failure (for example, heart, kidney and/or liver) due to low blood pressure (neutropenic sepsis). Symptoms may include fever, feeling or low blood pressure (light-headedness, dizziness), decreased urination, rapid pulse, rapid breathing (signs of neutropenic sepsis) <p>Some serious side effects may only be known through tests. This includes low blood cell counts due to a problem with the bone marrow or blood cancer starting from the bone marrow (myelodysplastic syndrome, acute myeloid leukaemia)</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>

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.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via

<https://nzphvc.otago.ac.nz/reporting>.

7. Product details

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

What ZEJULA tablets contain

Active ingredient (main ingredient)	niraparib
Other ingredients (inactive ingredients)	crospovidone ferrosoferric oxide lactose monohydrate magnesium stearate microcrystalline cellulose polyethylene glycol polyvinyl alcohol povidone purified talc silicon dioxide titanium dioxide
Potential allergens	lactose monohydrate

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

What ZEJULA tablets look like

ZEJULA tablets are grey oval shaped film-coated tablets debossed with "100" on one side and "Zejula" on the other side.

The tablets are available in blister packs of 56 or 84 tablets.

Who distributes ZEJULA tablets

GlaxoSmithKline NZ
Private Bag 106600
Downtown Auckland
New Zealand
Ph: (09) 367 2900
Fax: (09) 367 2910

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