



STARTING YOUR JOURNEY WITH ZEJULA▼ (NIRAPARIB)

A guide for patients with advanced ovarian cancer
who have been prescribed ZEJULA

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the product package leaflet. You can also report side effects directly to HPRA Pharmacovigilance on their website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

You have received this brochure because **you have been prescribed ZEPJULA after completing chemotherapy**. ZEPJULA is given to women who have been treated with chemotherapy. Your treatment with ZEPJULA is what is described as a “maintenance treatment”. By taking your ZEPJULA every day, as prescribed, it may help maintain the effect of chemotherapy, delay the progression of the disease and offer more time without the cancer recurring.

This brochure has been developed to provide information on some of the questions you may have about ZEPJULA and to **help support you on your treatment journey**.

This brochure is not intended to take the place of information and advice provided to you by your healthcare professional team, but to supplement it.

This item is intended for patients who have been prescribed ZEPJULA. For full information, please refer to the patient information leaflet that came with the medication.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed on this leaflet or in the product package leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

Should you have further questions and/or concerns about your treatment or about your illness, **please speak with your healthcare professional**.



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Ovarian cancer is one of the most commonly occurring cancers in women

When someone has cancer, the affected cells grow and multiply more quickly than normal, which causes the cancer cells to damage healthy tissue. In ovarian cancer, the cancer cells come from the ovary.

The usual treatment approach for women who are diagnosed with advanced ovarian cancer is a combination of surgery and chemotherapy followed by maintenance therapy. In some patients there can be a disappearance of all signs and symptoms of cancer (known as **'complete remission'**), even though the cancer may still be in the body, while in other patients some, but not all, signs and symptoms have disappeared (known as **'partial remission'**). For many women the cancer returns within a few years of this initial treatment. This is known as **'recurrence'**.



The exact cause of ovarian cancer is largely unknown, but it is likely that **multiple factors**, including genetics and lifestyle, **can increase the risk** of someone developing the disease.

Your healthcare professional has prescribed you with ZEPJULA as a second-line maintenance treatment for ovarian cancer.

Maintenance treatment is given to people whose cancer has responded to chemotherapy. It is given after chemotherapy has finished and may delay the return of the cancer.

It is important to recognise that maintenance therapy requires commitment to treatment over the long-term, but by doing so offers you a chance for more time without the cancer recurring – and **more time living life on your terms.**

What is ZEPJULA?

ZEPJULA is a **once-daily, oral maintenance therapy for advanced ovarian cancer.** It is used in adult women for the maintenance treatment of cancer of the ovary, the fallopian tubes, or the peritoneum (the membrane lining of the abdomen). As maintenance treatment, ZEPJULA is used to help maintain your response to standard platinum-based chemotherapy. ZEPJULA can be given to all women who have responded to chemotherapy, regardless of certain genetic characteristics.

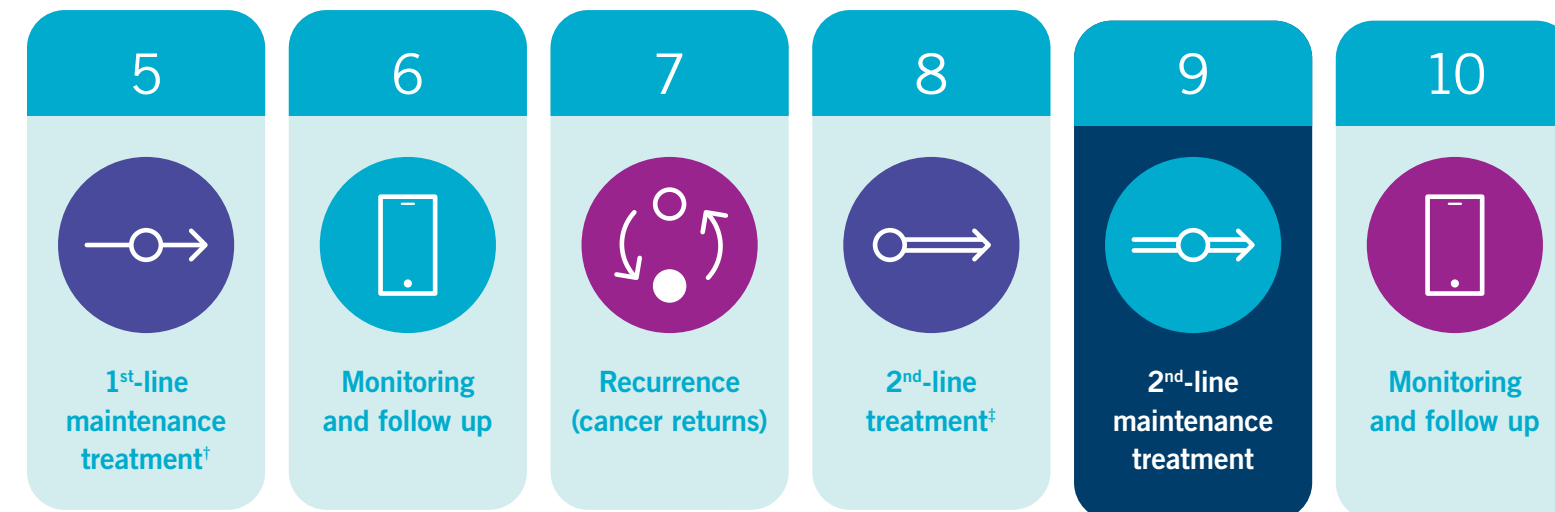
With you on your journey

Your experience with ovarian cancer is just that – yours. **It's a journey that is unique to you**, what you've been through, your challenges, and your specific needs. After your cancer comes back a second time, it is likely you will have discussed with your healthcare professional where you currently are in terms of your own journey.

*Usually a combination of surgery and chemotherapy
 †Not all patients receive this
 ‡Possibly further surgery



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How does ZEPJULA work?

ZEPJULA is part of a group of medications known as **PARP inhibitors**. PARP, or poly (ADP-ribose) polymerase, is a protein that helps repair damaged DNA, which allows cells to divide and multiply.

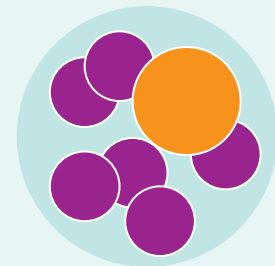
For normal cells: PARP activity is needed to help keep tissues in the body healthy

For cancer cells: PARP activity should be blocked to prevent tumour growth

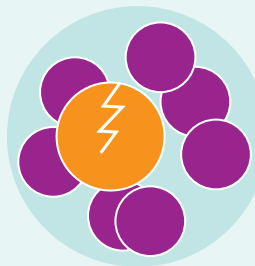


PARP inhibitors

As a PARP inhibitor, **ZEPJULA can prevent cancer cells from repairing themselves** and ultimately causes cancer cells to die. This may slow the progression or return of the cancer. However, ZEPJULA can also impact other cells and tissues in the body.



Cancer cells function in many ways like healthy cells.



Cancer cells also get DNA damage throughout their life and use PARP to repair themselves.



Reducing PARP activity with a medicine like ZEPJULA means that the DNA damage can't be fixed, so the DNA gets more and more damaged, which can lead to death of the cancer cell.

Healthy cells

Cancer cells

ZEPJULA

How do I take ZEPJULA?

ZEPJULA is an oral medication, which is taken once at the same time every day, making it easy to fit into your schedule. This means you don't have to travel to a hospital or clinic for treatment, leaving you with more time to focus on what matters to you.



ZEPJULA is a **once-daily oral medication** in the form of 100 mg hard capsules. Your **doctor will tell you how many capsules to take**. If you are not sure, check with your doctor, nurse or pharmacist.



The **dose should be taken around the same time each day**. You can choose a time that's most suitable to you and so it is easy to make taking ZEPJULA part your daily routine



ZEPJULA **can be taken with or without food**, which means you are not tied to meal schedules



Capsules should be **swallowed whole with water** and not crushed or chewed



Taking ZEPJULA at bedtime may help to manage nausea.



What if I miss a dose or vomit after taking it?

If you forget to take ZEPJULA or vomit after taking it, take your next dose at the usual scheduled time the following day. **Do not take an extra dose to make up for the one you missed.**

It is important to stick with your treatment plan. You should keep taking ZEPJULA regularly. Do not stop taking your treatment without consulting with your healthcare professional first.

Your treatment with ZEPJULA will be initiated by your healthcare professional who will also determine your starting dose.

Because ZEPJULA can cause changes to your blood, your healthcare professional will monitor your complete blood counts and your blood pressure while you are taking the treatment. These tests will include:



Blood cell count levels

- Weekly for the first month
- Monthly for the next 10 months
- As needed after 11 months



Blood pressure

- Weekly for the first 2 months
- Monthly for the next 10 months
- As needed after 12 months

If you experience any side effects, your healthcare professional may make dosage changes or in some cases, may choose to pause your treatment to allow any side effects to reduce or subside. There is more information about side effects in the following pages.

Your healthcare professional will find the best dosage for you. By working with your healthcare professional to **tailor your dose** of ZEPJULA, you may be able to stay on and benefit from your treatment for longer. Studies also show that even when the dose had to be reduced due to side effects, ZEPJULA remained effective.

How long should I continue taking ZEPJULA?



Although there is no set treatment timeline for ZEPJULA, it is really important to **take ZEPJULA continuously**, as prescribed, to help prevent your cancer from returning.

If you stop taking ZEPJULA, your cancerous cells will be able to repair themselves and start growing once again.

Always speak to your healthcare professional if you have any questions or concerns about your treatment.

As with other anti-cancer treatments, ZEPJULA may cause side effects. This may not be the case for every patient, but you should be aware and prepared for them.

The most common side effects with ZEPJULA include:

- Heart not beating regularly
- Nausea
- Constipation
- Vomiting
- Pain in the stomach area
- Mouth sores
- Diarrhoea
- Indigestion or heartburn
- Dry mouth
- Feeling tired
- Decreased appetite
- Urinary tract infection
- Shortness of breath
- Cough
- Rash
- Changes in blood test results
- Headache
- High blood pressure
- Dizziness
- Abnormal taste in mouth
- Trouble sleeping
- Anxiety
- Runny or stuffy nose
- Feeling of weakness
- Pain in the joints, muscles, and back

For a complete list of the side effects that may be experienced, please refer to the patient information leaflet that came with the medication.

What if I have side effects?

While taking ZEPJULA it is important to be mindful of how you feel and **let your healthcare professional know about any side effects** that you experience.

Your healthcare professional may have ideas for ways you can address the side effects that you are experiencing. For example, taking ZEPJULA before bed or by suggesting other ways to minimise them.

Your healthcare professional may interrupt your treatment with ZEPJULA for up to 28 days. They will determine when you can resume taking ZEPJULA and may reduce the number of capsules you take each day. This dose interruption and adjustment is to allow your blood counts or other severe side effects to improve.

Following this, you may be asked to make adjustments in the schedule of your blood tests.

Tell your healthcare professional immediately if you notice any of the following side effects, as these may require urgent medical treatment:

 Bruising, or bleeding for longer than usual if you hurt yourself **May be signs of a low blood platelet count (thrombocytopenia)**

 Being short of breath, feeling very tired, or having pale skin or a fast heartbeat **May be signs of a low red blood cell count (anaemia)**

 High temperature (fever) or infection **May be signs of a low white blood cell count (neutropenia)**

 A rise in blood pressure **May be a sign of high blood pressure (hypertension)**



Talk to your healthcare professional

As well as discussing any side effects, it is important you **maintain an open dialogue with your healthcare professional.**

Before you start taking ZEPJULA, tell your healthcare professional about any previous and current medical problems. It is also very important to discuss any new medical changes you experience whilst taking ZEPJULA.

These include if you:



Have (or have had) heart problems



Have (or have had) high blood pressure



Are pregnant or plan to become pregnant*



Are breastfeeding or plan to start breastfeeding†



If you are of child-bearing age, you must be on some form of effective contraception and remain on it for at least 1 month after taking your last dose



Are planning on driving or using machinery‡



Are taking other medications or planning on starting a new medication while taking ZEPJULA§



Develop an allergy or have a reaction to lactose or tartrazine

A rare reversible neurological condition named Posterior Reversible Encephalopathy Syndrome (PRES) has been associated with Zepjula maintenance treatment. It can present with symptoms including seizures (fits), headache, confusion, and changes in vision, with or without associated high blood pressure. Please contact your doctor if you have any of these symptoms.

*It is advised not to take ZEPJULA when pregnant

†ZEPJULA may be harmful to the baby, therefore you should not breastfeed while taking ZEPJULA

‡Take extra precautions because taking ZEPJULA can make you feel dizzy, light-headed and/or tired

§Speak to your healthcare team before you start any new medications, including prescription, over-the-counter medications, vitamins and herbal supplements



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