



*Your guide to treatment
with ZEJULA (niraparib)*

**An information booklet intended for women
who are starting maintenance treatment with ZEJULA**

Always refer to your healthcare professional and the patient information leaflet for more information

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine. Adverse events can also be reported to GSK Limited on +44 (0) 800 221 441 or at uksafety@gsk.com

1 DAILY DOSE

Zejula
niraparib
tablets 100 mg

YOUR JOURNEY IS AS UNIQUE AS YOU ARE

Your experience with ovarian cancer is exactly that – yours. As you move forward after a complete or partial response to platinum-based chemotherapy, your doctor has prescribed maintenance therapy with niraparib, also called ZEPJULA.

This booklet aims to provide you, and your family or carer, with the information needed to better understand ZEPJULA. This includes how it works, how to take it and what to expect from treatment.

If you feel concerned or have questions about your condition or treatment, you should speak to your doctor, nurse or pharmacist. At the back of this booklet is a notes page where you can jot down any questions or concerns you have.

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ABOUT YOUR TREATMENT

Why have I been prescribed ZEPJULA?

ZEPJULA is used in adult women for the treatment of cancer of the ovary, the fallopian tubes, 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.

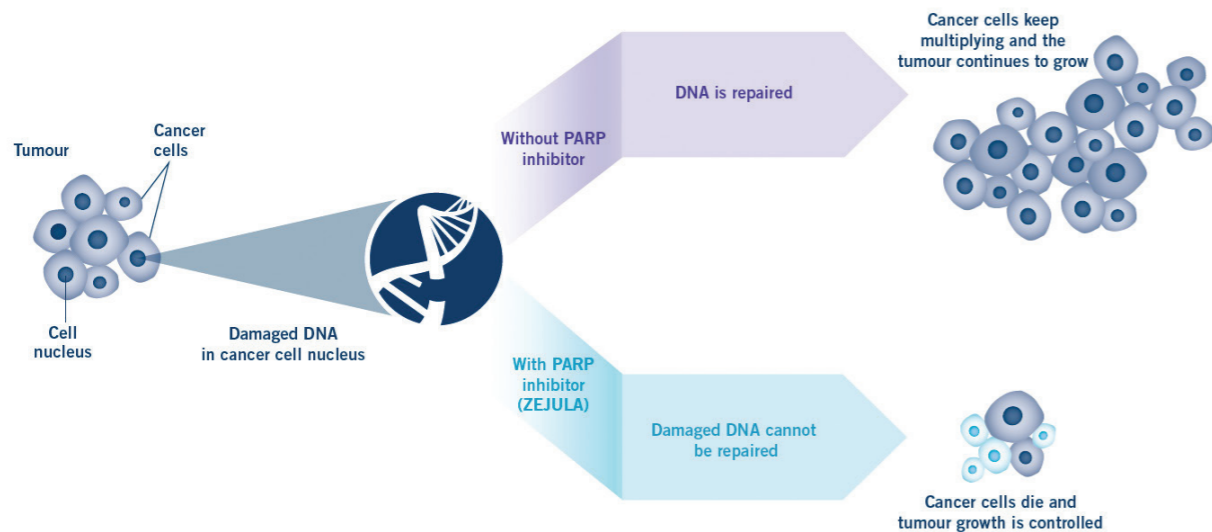
What is maintenance treatment?

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.

Please refer to the Patient Information Leaflet for further details regarding your ZEPJULA treatment.

HOW ZEJULA 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



HOW TO TAKE ZEJULA

ZEJULA is available as tablets that are taken once a day. Your doctor will tell you how many tablets to take. If you are not sure, check with your doctor, nurse or pharmacist.



Tablets should be swallowed whole with water



If you miss a dose or vomit after taking it, do not take an extra dose; take your next dose at its scheduled time



Taking ZEJULA at bedtime may help to manage nausea



It is advised to take ZEJULA tablets without food (at least 1 hour before or 2 hours after a meal) or with a light meal

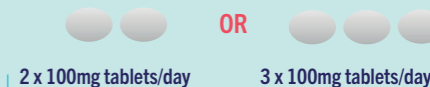


The dose should be taken around the same time each day



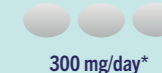
If you take more than you should, please contact your doctor

Maintenance after response to primary treatment



Your doctor will evaluate your baseline weight and blood platelet count to determine the appropriate starting dose for you.

Maintenance after recurrence



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

Please note, the tablet icons in this diagram are for representative purposes only and may look different to the tablets you are taking.

Please refer to the Patient Information Leaflet for further details regarding your ZEJULA treatment.

POSSIBLE SIDE EFFECTS

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

What are the very common side effects?

The following side effects are very common (meaning that they may affect more than 1 in 10 patients):

- Abnormal blood tests: Decreased number of overall white cells in the blood (leukopenia) or in a type of white blood cell (neutropenia), Decreased number of platelets in the blood (thrombocytopenia), Decreased number of red cells in the blood (anaemia)
- Feeling sick (nausea)
- Heartburn (dyspepsia)
- 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)

Other less common side effects may also occur. Please consult your healthcare professional if you have any concerns about side effects while taking ZEJULA.

ZEJULA may cause you to feel weak, unfocused, tired, confused or dizzy. If you experience any of these side effects, please use caution when driving or using machines. Further Information can be found in the accompanying patient information leaflet of this medicine.

What do I need to tell my healthcare professional whilst taking ZEJULA?

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at 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.

Tell your healthcare professional immediately if you notice any of the below very common serious side effects, as they may require you to seek 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 reduction in the number of white blood cell

May be a sign of Leukopenia

Please refer to the Patient Information Leaflet for a full list of common and rare side effects which may require you to seek urgent medical treatment.

If you become pregnant while you are taking ZEJULA or within one month of your last dose, contact your healthcare professional immediately.

MONITORING REQUIRED WITH ZEJULA

Why is regular monitoring of side effects important when taking ZEJULA?

Your dose of ZEJULA is based on a number of factors that your healthcare professional will check regularly.

Because ZEJULA can cause changes to your blood counts, your healthcare professional will monitor your complete blood counts and blood pressure while you are taking the treatment. During the first month of treatment, complete blood counts of red blood cells, white blood cells and platelets will be monitored weekly. Thereafter, blood counts will be monitored monthly for 10 months then as needed after 11 months.

Your blood pressure will be monitored at least weekly for the first two months of treatment. Following this, it will be monitored monthly for the first year of treatment, and then periodically after the first year of treatment.

If your blood counts and/or your blood pressure changes, your healthcare professional may adjust your dose. Dose adjustments and treatment breaks for up to 28 days may be necessary to ensure you recover fully from any side effects. However, if you experience serious side effects your doctor may recommend stopping Zejula treatment altogether.

The length of time you need to take ZEJULA for is not fixed. **You should continue taking ZEJULA until your doctor tells you to stop.**



Monitoring Blood cell counts

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





Monitoring Blood pressure

- Weekly for the first 2 months
- Monthly thereafter for the first year
- As needed after 12 months

Please refer to the Patient Information Leaflet for further details regarding your ZEJULA treatment.

MONITORING SCHEDULE

VISIT NO.	TIME 	DATE 

RESULTS

VISIT NO.	BLOOD COUNTS 	BLOOD PRESSURE 

What do I need to tell my healthcare professional whilst taking ZEJULA?

If your medical condition changes while you are on treatment, it is important that you tell your healthcare professional as soon as possible. In particular, your healthcare professional needs to know if you:

- **Experience any side effects:** in particular, symptoms such as low blood-cell counts (short of breath, feeling very tired), fever or infection, abnormal bruising or bleeding, high blood pressure, headaches, vision changes, confusion or seizures, raised and itchy rash (hives) and swelling—sometimes of the face or mouth (angioedema), causing difficulty in breathing, and collapse or loss of consciousness. ZEJULA may also make you feel weak, unfocused, tired or dizzy which could **influence your ability to drive and use machines.**
- **Develop an allergy or have a reaction to lactose or tartrazine or any of the ingredients (excipients)**

- **Become pregnant or plan to become pregnant:** if there is a risk that you may become pregnant, you must use **highly effective** contraception while you are taking niraparib and for 6 months after your last dose. If you become pregnant while you are taking niraparib or within one month of your last dose, contact your healthcare professional immediately
- **Plan to breastfeed:** you should not breastfeed during treatment and for one month after your last dose
- **Have started taking any other medicines:** always inform your healthcare professional before taking any other medicines, including prescription and over-the-counter medicines, vitamins and herbal supplements

Taking an active role in your healthcare can be a positive step forward – remember to make use of the help and support available to you.

Emotional support for your care partner(s)

Your care partner(s) and/or family members want the best for you, but sometimes they may try to do too much.

Talking to your care partner(s) about maintenance treatment

It's important to talk to your care team, including family, about the next steps in your treatment pathway so that they understand maintenance treatment and how they can support you. Try to be open with how you're feeling and how they can help you.

Reach out for help

It's OK to ask for support. Sometimes people want to help but aren't sure what to do. Reach out to the people in your life who make you feel loved and supported and ask for what you need. To help you with these conversations, make a list of things you need and have it ready (for example, grocery shopping, walking the dog, daily or weekly check-ins).

Additional cancer support groups and resources

Becoming involved with a cancer support organisation may give you the opportunity to meet other people with similar experiences and connect you with resources you haven't considered. Explore the list of organisations in the next section for sources of help and support.

Please refer to the Patient Information Leaflet for further details regarding your ZEJULA treatment.

ADDITIONAL SUPPORT

Where can I find additional support?

Patient organisations can be a valuable source of additional information and support. Many staff members and volunteers are cancer survivors or relatives of those with cancer, and they can offer a unique point of view beyond what is offered by your healthcare professional.



Patient organisations

Ovacome

www.ovacome.org.uk
support@ovacome.org.uk
Support number 0800 008 7054 (for phone calls only)
Support number 07503 682311 (for phone calls, text messaging and WhatsApp)
52–54 Featherstone Street, London EC1Y 8RT

Ovarian Cancer Action

www.ovarian.org.uk
info@ovarian.org.uk
Contact number: 020 7380 1730
483 Green Lanes, London, N13 4BS

Target Ovarian Cancer

www.targetovariancancer.org.uk
support@targetovariancancer.org.uk
Nurse-led support line: 020 7923 5475
30 Angel Gate, London EC1V 2PT

Support may also be available from other organisations not listed here.

TIPS FOR HEALTH AND WELLNESS

There's more to health than just treatment. Healthy emotional and lifestyle habits can also help with the challenges you face. Over time, this may help you feel as though you're getting back into a routine.

Consider these holistic health tips:



Don't do it alone

Talk with others if you get bad news or face a problem



Stay busy

Find distractions to take your mind off your health



Keep a journal

Remember to acknowledge and release your feelings



Live in the moment

Embrace the people and activities that make you feel good



Find ways to relax

Try meditation, yoga, breathing exercises or other relaxation practices

Please refer to the Patient Information Leaflet for further details regarding your ZEJULA treatment.

KEEP TRACK OF HOW YOU FEEL

Your healthcare team will monitor your response to niraparib. If your doctor feels it's necessary, he or she may make adjustments to your dose or choose to stop your treatment. That's why it helps to keep track of how you are feeling and any side effects you may experience.

Don't stop taking niraparib or make any changes to your dose without first talking with your doctor.

TREND SPOTTING

Take time to record how you feel. You can start on page 15. Look for trends that may be helpful to share with your doctor. Is there anything you want to remember or tell your doctor? Learn more about certain things you will want to track and remember on page 16.

TAKING AN ACTIVE ROLE

Communicating openly with your doctor is important when taking an active role in your healthcare plan. Use the next pages to track how you're feeling, prepare questions, and take notes before, during and after each appointment, as needed. Every cancer experience is unique. Coming prepared to your appointments helps your healthcare team to help **you**.

KEY DATES:

My treatment goal is:

Side effects that I am experiencing:

My dose of Niraparib is:

Instructions from my healthcare team:

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I'm reminding myself by:

Trends I may have noticed:

NOTES FOR MY DOCTOR

Appointment date: Appointment time:

Questions I have for my doctor

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.....
.....

Since my last visit I've noticed

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Anything else I want my healthcare team to know

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Notes from the visit

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.....

Sometimes, it can feel like there's a secret language in healthcare

This easy-to-use glossary contains definitions of some terms that you may encounter during your treatment. Use this guide to look up words that you don't know. You'll find words related to ovarian cancer, clinical trials, biomarkers and more that can help keep you informed throughout your journey.

A

Active surveillance

A way to monitor your health after chemotherapy that may involve regular examinations and lab tests instead of medicine or medical treatments. This may also be called **watch and wait** or **watchful waiting**.

Adverse effect, adverse event or adverse reaction

An unexpected medical issue, such as a **side effect**, which occurs during or following a treatment. See also **side effect**.

Anaemia

A condition that occurs when the number of red blood cells in your body is low. See also **red blood cell**.

Adjuvant

Chemotherapy that is given after surgery to kill any remaining cancer cells, with the goal of reducing the chances of recurrence. See also **neoadjuvant** and **recurrence**.

B

Biomarker

An indicator that can be used to measure your body's response to a treatment, track a disease, or imply normal or abnormal health states. Cancer antigen 125 (also known as CA-125) is an example of a biomarker for ovarian cancer.

Biomarker status

The state of a biomarker. For example, in ovarian cancer, *BRCA* mutation is a biomarker whose status may be described as *BRCA*-positive or *BRCA*-negative.

Biopsy

A procedure that involves taking a small sample of your organ or tissue to check for cancer cells, and if the cancer has spread to that organ or tissue.

BRCA [pronounced as bracka or B-R-C-A]

Particular genes that produce proteins that help to prevent tumour growth. *BRCA* proteins help repair damaged DNA in cells. You may hear the terms *BRCA1* and *BRCA2*. Mutations in *BRCA* may mean that it no longer functions. A *BRCA* gene mutation can be inherited from a parent. When this happens,

it is known as a germline *BRCA* (*gBRCA*) mutation. When there is a mutation in *BRCA* that is not passed from a parent to a child, it is called a somatic *BRCA* (*sBRCA*) mutation. See also **BRCA mutation**, **BRCA-negative** and **BRCA-positive**.

BRCA mutation

Change in the *BRCA* gene. See also **BRCA mutation**, **BRCA-negative** and **BRCA-positive**.

BRCA mutation status

A broad term that reveals the results of genetic testing as *BRCA*-positive or *BRCA*-negative.

BRCA-negative (or BRCA wild-type or BRCA not mutated)

This means a change (also called a mutation) has not happened in the *BRCA* gene. A person without a mutation in the *BRCA* gene can still develop cancer. Being *BRCA*-negative just means that a gene mutation is not present. This may also be called *BRCA* wild-type (*BRCAwt*).

BRCA-positive (or BRCA mutation)

This means a change (also called a mutation) has been found in the *BRCA* gene. This may also be called *BRCA* mutation (*BRCAm*). A positive result or mutation does not mean that cancer will occur, but this puts you at a higher risk for certain cancers. See also **BRCA**.

C

Chemotherapy

A cancer treatment that works by stopping cancer cells from reproducing. This prevents them from growing and spreading in the body. There are many different types of chemotherapy, for example **platinum-based chemotherapy**.

Commercial plan/private insurance

A type of health insurance that covers medical expenses, such as visits to your doctor and prescription medications. Insurance available through an employer is an example of private insurance. This may also be called **commercial insurance**.

Complete blood count (CBC)

Measures the number of cells in your blood, including red blood cells, white blood cells and platelets. You will have regularly scheduled CBCs during treatment to help your doctor decide if you need to change your dose of niraparib. This may also be called a **blood count**.

D

Dose adjustment

Your healthcare team may adjust your dose of niraparib based on how you feel or the results of your blood tests and monitoring. This may also be called a **dose modification** or **dose reduction**.

E

Epithelial ovarian cancer

Cancer that occurs in cells on the surface of the ovary. This may also be called **ovarian epithelial cancer**.

F

First-line treatment

An initial treatment that is generally used to reduce cancer. In ovarian cancer this might be surgery and/or chemotherapy, potentially followed by a maintenance treatment. This may also be called frontline treatment.

G

Genetic characteristics

Traits inherited from your parents, such as certain gene mutations like *BRCA* or homologous recombination deficiency (HRD), commonly found in the cells of some types of cancers.

Grade

The grade tells you how much your cancer cells look like normal cells. It gives your doctor an idea of how the cancer might behave. The grade and **stage** help your doctor decide which treatment you need.

H

Haematologic abnormality

A count or level in your blood that is out of the ordinary. It may include low or high red blood cells, low white blood cells or low platelets. See also **complete blood count (CBC)**.

HRD

HRD, or homologous recombination deficiency, is a genetic characteristic where cells have trouble repairing their DNA. People who have HRD genetic characteristics may be BRCA-positive or BRCA-negative. See also **HRD-positive**.

HRD-positive

A positive test result means your cells have a deficiency that causes difficulty repairing themselves. A positive result does not mean that cancer will occur, but this puts you at a higher risk for certain cancers. See also **HRD**.

I

Insurance company (or insurer)

The organisation or company that provides and manages private medical and prescription drug insurance. This may also be called **carrier**, **health plan** or **payer**.

M

Maintenance treatment

A treatment given to a patient after cancer has responded to platinum-based chemotherapy. It is not chemotherapy, and it may help delay the time before cancer comes back.

Median

The middle number in a set of data, also called the midpoint. It means that half of the numbers are greater than the median, and half are less.

Mindfulness

A way to help reduce stress by focusing your attention on the present moment and accepting your thoughts and feelings without judgement. See your Niraparib Planner for other tips on managing stress.

N

Neoadjuvant

Chemotherapy that is sometimes given to shrink the cancer before surgery, or is used if surgery is not an option. See also **adjuvant**.

Neutropenia

A condition that occurs when the number of your white blood cells (neutrophils) is low, which can put you at greater risk for infection. See also **complete blood count (CBC)**.

Neutrophil

The most common type of white blood cell, responsible for much of the body's protection against infection.

Niraparib

Also called ZEPJULA, it is a once-daily oral maintenance therapy for ovarian cancer. It is used for the maintenance treatment of cancer of the ovary, the fallopian tubes or the peritoneum. Niraparib is used after you have responded to previous treatment with standard platinum-based chemotherapy.

P

Package insert

This is an official document that is provided with every prescription medicine. The package insert explains what you need to know about a medicine, including who should take it, what it treats, how it works, how to take it and what to expect from treatment.

PARP inhibitor/PARP1 and PARP2 inhibitor

PARP, or poly(ADP-ribose) polymerase, is a family of proteins that helps repair damaged DNA in cells. A PARP inhibitor, like niraparib, may prevent cancer cells from repairing their damaged DNA, which can cause cancer cells to die. This may slow the return or progress of cancer. Niraparib can also impact other cells and tissues in the body.

Payer

The organisation or company that provides and manages your medical and prescription drug insurance, if you have it. This may also be called **carrier**, **health plan**, or **insurance company** (or **insurer**).

Personal Health Information (PHI)

Private data including, but not limited to, your full name, address, medical history and test results, which are collected by your healthcare team or health insurance company. These data can be used to identify an individual. PHI is subject to General Data Protection Regulation (GDPR).

Pharmacist

A healthcare provider who is trained to prepare prescription medicine and is focused on the safe and effective use of medication. If you have any questions about your medicine, your pharmacist is a good person to ask.

Phase 2 trial (or Phase 2 study)

A study that tests whether a new treatment works for a certain type of cancer or other disease.

Phase 3 trial (or Phase 3 study)

A study that tests the safety of a new treatment and how well the treatment works compared with a standard treatment.

Placebo

An inactive substance or other intervention that looks the same as, and is given the same way as, an active drug or treatment being tested in a trial.

Platelet

A cell that helps form blood clots to slow or stop bleeding and to help wounds heal. It is one of the cells that is reviewed as part of a complete blood count (CBC) test. See also **complete blood count (CBC)**.

Platelet count

A laboratory test that measures the number of platelets in your blood. Platelets are cells that help your blood to clot. It is one of the cells that is checked as part of a complete blood count (CBC) test. See also **complete blood count (CBC)**.

Platinum-based chemotherapy

A type of chemotherapy used to treat ovarian cancer that contains the metal platinum, such as carboplatin or cisplatin. It works by damaging DNA in cells, which stops them from reproducing.

Prescriber

The healthcare provider who wrote the prescription for your medicine or treatment.

Progression-free survival (PFS)

The length of time during and after treatment that you live with cancer, but your disease does not get worse.

R

Recurrence

When the cancer returns after a period of remission. See also **remission**.

Red blood cell

A blood cell that carries oxygen throughout the body. It is one of the cells that is reviewed as part of a complete blood count (CBC) test. See also **complete blood count (CBC)**.

Referral

A recommendation from a doctor that you should be examined or treated by another healthcare professional.

Remission

When the signs and symptoms of cancer are reduced. Remission can be partial or complete.

Response (complete or partial)

How cancer reacts to treatment. If some, but not all, signs or symptoms of cancer have disappeared, it is a partial response. If there are no remaining clinical signs of cancer, (which can be monitored by your doctor through imaging tests such as computerised tomography [CT] scan, magnetic resonance imaging [MRI] or positron emission tomography [PET] scan), it is considered a complete response, although this does not necessarily mean that the cancer has been cured. This may also be called **complete** or **partial remission**.

S

Second-line treatment

A treatment that is given after the return of the cancer or the initial (first-line) treatment has stopped working.

Self-management

Doing what is necessary to effectively manage your health.

Self-monitoring

Keeping track of your own day-to-day health, including how you're feeling, when you take your medicine, and any symptoms or side effects that you may experience. This information can help your doctor to better understand how you are doing. See your **Niraparib Planner** for other tips on self-monitoring, as well as dedicated pages for notes and tracking.

Side effect

An often harmful and unwanted effect of your medicine that occurs along with the desired effect. See also **adverse effect**, **adverse event** or **adverse reaction**.

Stage

The stage of a cancer tells you how big it is and whether it has spread. Ovarian cancer is divided into four stages. The stage and **grade** help your doctor decide which treatment you need.

T

Threshold

A set point or level at which something begins or changes.

Thrombocytopenia

A condition that occurs when the number of platelets in your blood is lower than the normal range. Platelets are needed to help your blood to clot. If your platelet level is low, you may experience bruising or bleeding more often.

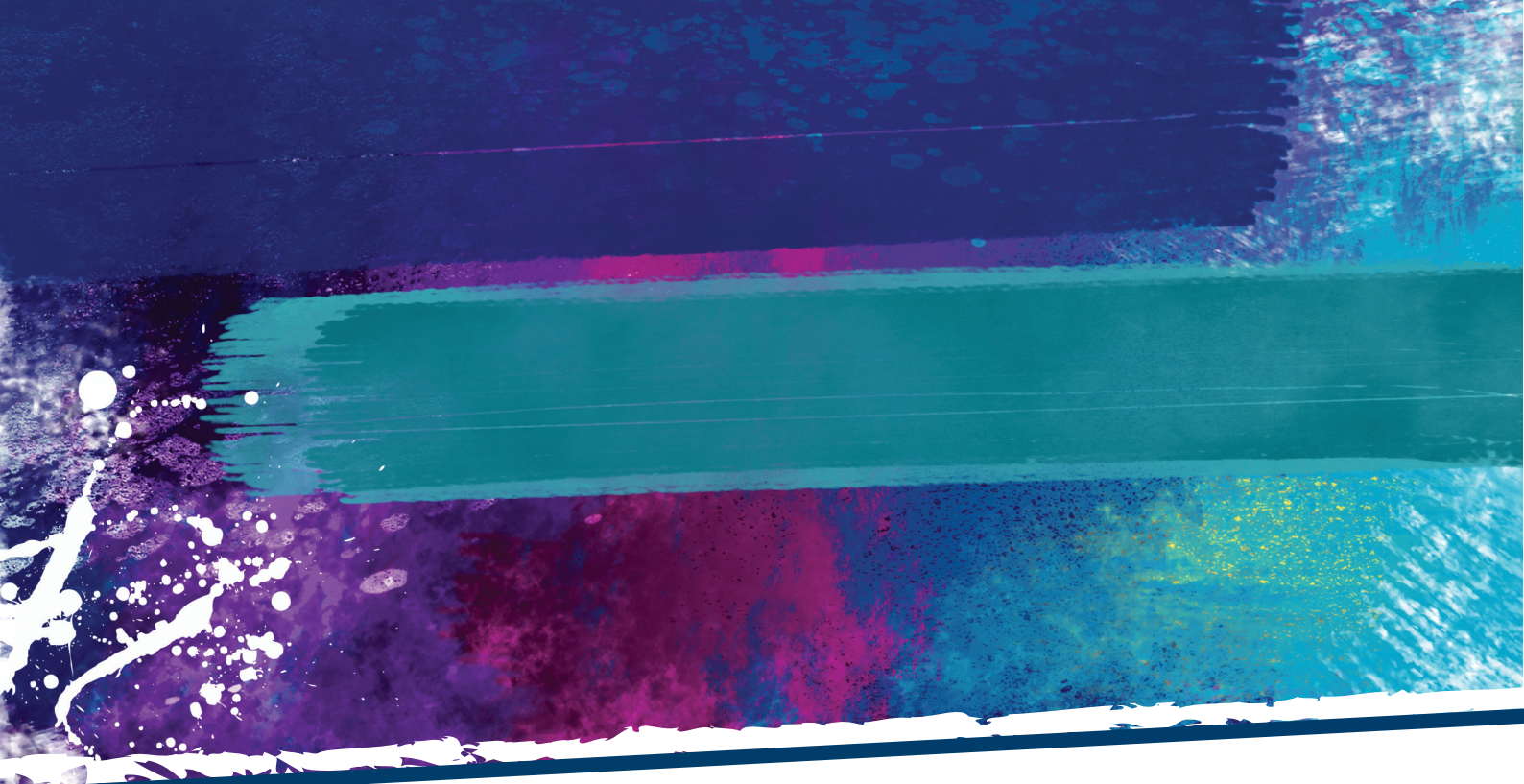
Treatment break

When you stop taking your treatment for a set period of time, for example to allow you to recover from a **side effect**.

W

White blood cell

A set point or level at which something begins or change



GSK

1 DAILY DOSE

Zejula
niraparib
tablets 100 mg

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