A GUIDE TO **SUPPORTING YOUR PATIENT** THROUGH **THEIR TREATMENT JOURNEY**

This document is designed for you to learn more about ZEJULA, and to assist you in providing support for ZEJULA patients.

Important Reminder:
Advise patients and care partners to review the Patient Information section in the Prescribing Information before starting ZEJULA.

For healthcare professional (HCP) use only. Do not share this guide with patients.

INDICATION

ZEJULA is indicated for first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) – positive status defined by either a deleterious or suspected deleterious *BRCA* mutation, and/or genomic instability.

IMPORTANT SAFETY INFORMATION

Myelodysplastic syndrome/acute myeloid leukemia (MDS/AML), including cases with a fatal outcome, have been reported in patients who received ZEJULA. In PRIMA, of patients within the HRD-positive population, MDS/AML occurred in 8 out of 245 (3.3%) patients treated with ZEJULA, and in 3 out of 125 (2.4%) patients treated with placebo with a follow-up of 6.1 years. The duration of therapy with ZEJULA in patients who developed secondary MDS/cancer therapy-related AML varied from 5.5 months to 5 years. All patients who developed secondary MDS/cancer therapy-related AML had received previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy. For suspected MDS/AML or prolonged hematological toxicities, refer the patient to a hematologist for further evaluation. Discontinue ZEJULA if MDS/AML is confirmed.

Please see additional Important Safety Information throughout, as well as the accompanying full Prescribing Information for ZEJULA.

BRCA, breast cancer susceptibility gene.

GSK

Help your patients learn more about PARP inhibitors like ZEJULA

What is ZEJULA?

- ZEJULA is an infusion-free maintenance treatment, not a chemotherapy[1,2]
- ZEJULA is a type of targeted therapy that **inhibits poly (ADP-ribose) polymerase (PARP) enzymes**[1]

ZEJULA inhibits PARP1 and PARP2, leading to cancer cell death in preclinical studies.[1]
Because all cells use PARP, PARP inhibitors may also affect healthy cells and tissues.[3]

Single-Strand Break
PARP inhibition interferes with DNA repair, leading to accumulation of single-strand breaks (SSBs).[1,3]

Double-Strand Break
SSBs become double-strand breaks (DSBs), which are not repaired due to deficient DNA repair pathways present in many ovarian tumors.[4]

Cell Death
Persistent DSBs that cannot be repaired lead to programmed cell death.[4]

In vitro studies suggest that ZEJULA's cytotoxic effects may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, apoptosis, and cell death.[1]

The clinical significance of in vitro studies is unknown. Mechanism of action statements are not meant to imply clinical significance.

After chemotherapy, which works to damage and kill cancer cells, ZEJULA steps in to help keep cancer from returning.[1,2,5]

DISCUSS

Talk to your patients about:

- Why they are a candidate for maintenance treatment
- How ZEJULA may help them
- What potential side effects they may experience

IMPORTANT SAFETY INFORMATION (continued)

Hematologic adverse reactions (thrombocytopenia, anemia, neutropenia, and/or pancytopenia) have been reported in patients receiving ZEJULA. The overall incidence of Grade ≥3 thrombocytopenia, anemia, and neutropenia were reported, respectively, in 39%, 31%, and 21% of patients receiving ZEJULA in PRIMA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 4%, 2%, and 2% of patients in PRIMA. In patients who were administered a starting dose of ZEJULA based on baseline weight or platelet count in PRIMA, Grade ≥3 thrombocytopenia, anemia, and neutropenia were reported, respectively, in 22%, 23%, and 15% of patients receiving ZEJULA.

Please see additional Important Safety Information throughout, as well as the accompanying full Prescribing Information for ZEJULA.

Explain to your patients why 1L maintenance treatment with ZEJULA may be a potential treatment option for them

1 DAILY DOSE
Zejula niraparib tablets 100/200/300 mg

Who can receive ZEJULA?

Adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) – positive status.[1]

ZEJULA is an oral, once-daily, PARPi monotherapy for HRD-positive patients with an individualized starting dose[1]

CALENDAR 3 months

Patients should start treatment no later than 12 weeks after their most recent platinum-containing regimen[1]

200 mg/day — **If baseline weight <170 lb OR platelets <150,000/µL**

300 mg/day — **If baseline weight ≥170 lb AND platelets ≥150,000/µL**

Continue treatment with ZEJULA until disease progression or unacceptable toxicity.[1]

For patients with moderate hepatic impairment,[a] the recommended dosage of ZEJULA is 200 mg once daily, regardless of body weight or platelet count. Monitor patients for hematologic toxicity and reduce the dose, if needed.[1]

[a]Total bilirubin ≥1.5 to 3 x ULN and any AST level.[1] As defined by the National Cancer Institute-Organ Dysfunction Working Group (NCI-ODWG) criteria.

There are no data in patients with severe hepatic impairment, severe renal impairment, or end-stage renal disease undergoing hemodialysis.[1]

No dose adjustment necessary for mild hepatic impairment (total bilirubin <1.5 x ULN and any AST level or bilirubin ≤ULN and AST >ULN) and for age ≥65 years).[1]

IMPORTANT SAFETY INFORMATION (continued)

Hematologic adverse reactions (continued) Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 3%, 3%, and 2% of patients. Do not start ZEJULA until patients have recovered from hematological toxicity caused by prior chemotherapy (≤Grade 1). Monitor complete blood counts weekly for the first month, monthly for the next 11 months, and periodically thereafter. If hematological toxicities do not resolve within 28 days following interruption, discontinue ZEJULA, and refer the patient to a hematologist for further investigations.

1L, first-line; AST, aspartate aminotransferase; HRD, homologous recombination deficient; PARPi, poly (ADP-ribose) polymerase inhibitor; ULN, upper limit of normal.

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Discuss potential side effects patients may experience when starting or taking ZEJULA

- Remind patients that their healthcare provider will periodically monitor blood counts, blood pressure, and heart rate to help identify if dosing needs to be modified during treatment with ZEJULA[1]
- Advise your patient to tell their healthcare provider about all of their medical conditions, including heart problems, liver problems, high blood pressure, pregnancy, and breastfeeding[1]
- Remind your patients to tell their healthcare provider about all of the medicines they are taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements[1]

Please see additional Important Safety Information throughout, as well as the accompanying full Prescribing Information for ZEJULA.

Walk your patients through how to take ZEJULA

1 DAILY DOSE
Zejula niraparib tablets 100/200/300 mg

ZEJULA can be taken:

With or without food[1]

At home or on the go[1,a,b]

At any time of day or night[1,c]

Taking ZEJULA before bed may help reduce nausea.[1]

[a]Routine monitoring of blood counts, blood pressure, and heart rate is required as part of treatment with ZEJULA.[1] [b]Tablets must be stored and dispensed in original container. Store at room temperature (68°F to 77°F).[1] [c]ZEJULA should be taken at approximately the same time each day.[1]

Tablet should be swallowed whole. Do not crush, chew, or split tablet.[1] If a patient vomits or misses a dose, an additional dose should not be taken. The next dose should be taken at its regularly scheduled time.[1]

DISCUSS

Support patients starting or taking ZEJULA

- What additional questions do you have about how to take ZEJULA?
- Support strategies for patients to maintain a regular schedule for taking ZEJULA:
  - Suggest using diaries, calendars, and alarms on clocks or mobile phones[6]
  - Recommend a routine, which includes taking ZEJULA at the same time each day[6]
  - Engage with care partners on how they may support patient's routine[6]

IMPORTANT SAFETY INFORMATION (continued)

Hypertension and cardiovascular effects have been reported in patients receiving ZEJULA. Grade 3-4 hypertension occurred in 6% of patients receiving ZEJULA vs 1% of patients receiving placebo in PRIMA, with no reported discontinuations. Monitor blood pressure and heart rate at least weekly for the first two months, then monthly for the first year, and periodically thereafter during treatment with ZEJULA. Closely monitor patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension. Manage hypertension with antihypertensive medications and adjustment of the ZEJULA dose if necessary.

Help your patients understand how monitoring can inform their healthcare team if a change needs to be made to their dose

Monitoring complete blood counts, blood pressure, and heart rate helps identify the need to dose modify[1]

	ONCE A WEEK	ONCE A MONTH	ONCE EVERY 2-3 MONTHS
BLOOD COUNTS	1ST MONTH	REST OF YEAR	AFTER YEAR 1[a]: MONITOR PERIODICALLY
BLOOD PRESSURE AND HEART RATE	1ST AND 2ND MONTHS	REST OF YEAR	AFTER YEAR 1[a]: MONITOR PERIODICALLY

If myelodysplastic syndrome or acute myeloid leukemia (MDS/AML) is confirmed, discontinue ZEJULA.[1]

[a]Monitor periodically. Per physician discretion.

Healthcare providers may change patients dose, temporarily stop treatment, or permanently stop treatment with ZEJULA if patients have certain side effects.[1]

ASK

Encourage patients to be proactive in their treatment and explain how these appointments will be scheduled:

- Do you anticipate any challenges in keeping your next appointment?

IMPORTANT SAFETY INFORMATION (continued)

Posterior reversible encephalopathy syndrome (PRES) occurred in 0.1% of 2,165 patients treated with ZEJULA in clinical trials and has also been described in postmarketing reports. Monitor all patients for signs and symptoms of PRES, which include seizure, headache, altered mental status, visual disturbance, or cortical blindness, with or without associated hypertension. Diagnosis requires confirmation by brain imaging. If suspected, promptly discontinue ZEJULA and administer appropriate treatment. The safety of reinitiating ZEJULA is unknown.

Clarify for your patients that dose modifications may help manage adverse reactions

Depending on a number of factors, patients taking ZEJULA may require a dose adjustment

Non-hematologic

- CTCAE >3 Grade 3 AR that persists despite management

Hematologic

- Hematologic ARs requiring transfusion
- Thrombocytopenia: platelet count <100,000/µL
- Neutrophil count <1,000/µL
- Hemoglobin count <8 g/dL

Interrupt treatment for up to 28 days[a]

Resume at reduced dose following resolution

Obtain CBC weekly[b]

Resume at same[c] or reduced dose following resolution

Continue CBC weekly for an additional 4 weeks[d]

[a]If hematological toxicities do not resolve within 28 days following interruption, discontinue ZEJULA and refer the patient to a hematologist for further investigation.[1] [b]Monitor blood counts weekly until platelet counts return to ≥100,000/µL and neutrophil counts return to ≥1,500/µL or hemoglobin returns to ≥9 g/dL.[1] [c]Resume at the same dose only for the first occurrence of thrombocytopenia if platelets are >75,000/µL.[1] [d]This recommendation is per the PRIMA clinical study protocol.[7]

ASK

Do you understand the importance of monitoring to ensure proper dose modifications?

IMPORTANT SAFETY INFORMATION (continued)

Embryo-fetal toxicity and lactation: Based on its mechanism of action, ZEJULA can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months after receiving their final dose of ZEJULA. Because of the potential for serious adverse reactions from ZEJULA in breastfed infants, advise lactating women not to breastfeed during treatment with ZEJULA and for 1 month after receiving the last dose.

Please see additional Important Safety Information throughout, as well as the accompanying full Prescribing Information for ZEJULA.

AR, adverse reaction; CBC, complete blood count; CTCAE, Common Terminology Criteria for Adverse Events.

Help your patients to understand what dose modification means

To manage adverse reactions, consider interruption of treatment, dose reduction, or dose discontinuation[1]

If baseline weight: <170 lb OR platelets: <150,000/µL

STARTING DOSE[a]:	FIRST DOSE REDUCTION:	SECOND DOSE REDUCTION:
200 mg/day	100 mg/day	Discontinue

If baseline weight: ≥170 lb AND platelets: ≥150,000/µL

STARTING DOSE[a]:	FIRST DOSE REDUCTION:	SECOND DOSE REDUCTION:	THIRD DOSE REDUCTION:
300 mg/day	200 mg/day	100 mg/day	Discontinue

[a]Patients should start treatment with ZEJULA no later than 12 weeks after their most recent platinum-containing regimen. Continue treatment with ZEJULA until disease progression or unacceptable toxicity.[1]

For patients with moderate hepatic impairment,[b] the recommended dosage of ZEJULA is 200 mg once daily, regardless of body weight or platelet count. Monitor patients for hematologic toxicity and reduce the dose, if needed.[1]

[b]Total bilirubin ≥1.5 to 3 x ULN and any AST level.[1] As defined by the National Cancer Institute-Organ Dysfunction Working Group (NCI-ODWG) criteria.

Adverse reactions in the PRIMA study led to dose reduction or interruption in 79% of patients, most frequently (>10%) from thrombocytopenia (53%), anemia (32%), and neutropenia (19%).[1]

DISCUSS

Share information with your patient about how to identify and manage adverse reactions while taking ZEJULA. Describe when a dose modification may be recommended.

- What questions do you have about starting ZEJULA?
- What follow-up questions do you have about dose modification?

AST, aspartate aminotransferase; ULN, upper limit of normal.

Please see additional Important Safety Information throughout, as well as the accompanying full Prescribing Information for ZEJULA.

Guide your patients about what to expect and potential side effects

Symptoms of low blood counts may indicate serious bone marrow problems[1]

Advise patients to contact their healthcare provider if laboratory tests find low blood counts, or a need for transfusion, and/or if they experience any of the following symptoms.[1]

Symptoms of low blood counts may include[1]:

- **Weakness**
- **Feeling tired**
- **Weight loss**
- **Frequent infections**
- **Fever**
- **Shortness of breath**
- **Blood in urine or stool**
- **Bruising or bleeding easily**

These symptoms may be a sign of hematological toxicity or myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML).[1]

Discontinue ZEJULA if MDS/AML is confirmed.[1]

These are not all the possible side effects of ZEJULA. Encourage patients to **call their doctor for medical advice** about side effects.

Patients may report side effects to the US Food and Drug Administration (FDA) by calling 1-800-FDA-1088.

Additional serious side effects may include high blood pressure and PRES. For more information, see the Patient Information section of the Prescribing Information.[1]

ASK

Encourage patients to take an active role in their care by keeping a record of experienced side effects and timing

- What questions do you have about possible side effects with ZEJULA?

IMPORTANT SAFETY INFORMATION (continued)

First-line Maintenance Treatment of HRD-Positive Advanced Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of all patients who received ZEJULA in PRIMA were thrombocytopenia (66%), anemia (65%), nausea (62%), fatigue (52%), musculoskeletal pain (46%), neutropenia (43%), constipation (40%), leukopenia (29%), headache (27%), insomnia (25%), vomiting (23%), dyspnea (21%), decreased appetite (20%), dizziness (20%), cough (20%), hypertension (20%), AST/ALT elevation (14%), acute kidney injury (13%), and anxiety (12%).

Common lab abnormalities (Grades 1-4) in ≥25% of all patients who received ZEJULA in PRIMA included: decreased hemoglobin (85%), decreased leukocytes (72%), decreased platelets (71%), decreased neutrophils (64%), increased glucose (62%), decreased lymphocytes (55%), increased alkaline phosphatase (48%), increased creatinine (40%), decreased magnesium (39%), increased AST (35%), increased ALT (32%), and increased calcium (31%).

ALT, alanine aminotransferase; AST, aspartate aminotransferase; HRD, homologous recombination deficient; PRES, posterior reversible encephalopathy syndrome.

GSK

Be present and support your patients during their treatment with ZEJULA

Help your patients understand the importance of taking an active role in their treatment journey

Empower your patient with information about maintenance treatment

- Encourage patients to **discuss maintenance treatment with their healthcare team** during their chemotherapy

Embrace the provider-patient relationship

- Before starting treatment with ZEJULA, advise patients about **dosing, monitoring, and management of possible side effects**
- Encourage patients to **tell their healthcare team** about all medical conditions and any medicines they take before starting treatment with ZEJULA
- Confirm patients **understand the importance of regular monitoring and testing** for serious side effects
- Encourage patients to **contact their doctor's office with any symptoms** they experience during the treatment

Ensure patients have all the information they need

- **Recommend strategies** for remembering to take their medication
- **Share resources** to help them find additional information
- Make sure they **know who to contact** with questions

Reach out to a ZEJULA representative to request patient resources, such as the Patient Starter Kit

[10] **Please see additional Important Safety Information throughout, as well as the accompanying full Prescribing Information for ZEJULA.**

Refer to online resources to further support your patient

1 DAILY DOSE Zejula niraparib tablets 100/200/300 mg

***Together with GSK Oncology* may have tools to support certain patients in specific financial situations**

The following ovarian cancer patient support organizations may provide additional resources:

For additional information, please visit these sites or contact these organizations. These resources are independent from GSK, they are not controlled or endorsed by GSK, and GSK is not responsible for their content.

National Ovarian Cancer Coalition
https://ovarian.org

OVARCOME
https://ovarcome.org

Ovarian Cancer Research Alliance
https://ocrahope.org

Additional support organizations

Visit https://zejula.com/resources/support-organizations or **SCAN THE QR CODE**.

Additional resource:

Oncology Nursing Society (ONS) Oral Anticancer Medication Toolkit: https://www.ons.org/sites/default/files/2023-05/23%20OAM%20toolkit.pdf

Resources for HCPs

About ZEJULA
Visit ZEJULAHCP.com or SCAN THE QR CODE.

Together with GSK Oncology

Resources for Patients

Patient Resources
Visit https://zejula.com/resources/zejula-my-way or SCAN THE QR CODE.

Patient Starter Kit

HCP, healthcare professional.

References

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1 DAILY DOSE
Zejula
niraparib
tablets 100/200/300 mg