FOR 1L MAINTENANCE TREATMENT OF ADULT PATIENTS WITH HRD-POSITIVE PLATINUM-RESPONSIVE ADVANCED OVARIAN CANCER[1]

1 DAILY DOSE

Zejula
niraparib
tablets 100/200/300 mg

Managing select adverse reactions for ZEJULA in 1L maintenance treatment

INDICATION

ZEJULA (niraparib) 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.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

1L, first-line; ***BRCA***, breast cancer susceptibility gene; **HRD**, homologous recombination deficient.

GSK

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.

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. 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.

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.

Please see additional Important Safety Information on the next page.

HRD, homologous recombination deficient.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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.

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%).

Please see the accompanying full Prescribing Information for ZEJULA.

ALT, alanine aminotransferase; **AST**, aspartate aminotransferase.

Contents

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

PRIMA was a double-blind, placebo-controlled trial in which patients (N = 733) in complete or partial response to first-line platinum-based chemotherapy were randomized 2:1 to ZEJULA or matched placebo. Efficacy was evaluated in 373 patients in the HRD-positive population.[1-3] PFS in the HRD-positive population was the primary endpoint evaluated by BICR, per RECIST v1.1, in the primary analysis (13.8-month follow-up). **HRD-positive population (n = 373):** median PFS with ZEJULA was 21.9 months (95% CI, 19.3-NE) vs 10.4 months (95% CI, 8.1-12.1) with placebo; HR, 0.43 (95% CI, 0.31-0.59, *P*<0.0001).[1,2]

ZEJULA offers an individualized starting dose that was observed to lower rates of select ARs while maintaining efficacy[1,4,5]

PRIMA prospectively evaluated the safety and efficacy of an individualized starting dose (n = 86) of either 200 mg or 300 mg, selected based on baseline weight and platelet count, as well as a fixed starting dose (n = 159) of 300 mg regardless of body weight or platelet count.[1,2] In patients taking an individualized starting dose, comparable efficacy was observed as measured by the HR for PFS. **HRD-positive population (n = 130):** HR, 0.39 (95% CI, 0.22-0.72)[1]; ***BRCA*m population (n = 53):** HR, 0.29 (95% CI, 0.13-0.67).[5] **These prespecified subgroup analyses were exploratory and not powered to detect a statistically significant treatment effect. Interpret results with caution.**

In the HRD-positive population, compared with patients who received either the fixed starting dose or the individualized starting dose (n = 245), ZEJULA's individualized starting dose (n = 86) was shown to reduce rates of Grade 3-4 anemia from 31% to 22%; thrombocytopenia from 38% to 16%; and neutropenia from 17% to 13%.[1]

AR, adverse reaction; **BICR**, blinded independent central review; ***BRCA*m**, breast cancer susceptibility gene-mutated; **CI**, confidence interval; **HR**, hazard ratio; **HRD**, homologous recombination deficient; **NE**, not estimable; **PFS**, progression-free survival; **RECIST**, Response Evaluation Criteria in Solid Tumors.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

A 1L maintenance treatment with an individualized starting dose for your patients[1]

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

ZEJULA is the only once-daily oral PARP inhibitor monotherapy available for eligible 1L platinum responders with HRD-positive advanced ovarian cancer.[1,6,7]

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

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

1L, first-line; **HRD**, homologous recombination deficient; **PARP**, poly (ADP-ribose) polymerase.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

ZEJULA: Recommended starting dose for patients with moderate hepatic impairment[1]

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

Total bilirubin ≥1.5-3x ULN and any AST level[a]

For patients with moderate hepatic impairment, 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.

No dose adjustments are necessary for patients with mild hepatic impairment (<1.5x ULN total bilirubin and any AST level OR bilirubin ≤ ULN and AST > ULN[a]).

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

[a]As defined by the National Cancer Institute - Organ Dysfunction Working Group (NCI-ODWG) criteria.

AST, aspartate transaminase; **ULN**, upper limit of normal.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

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

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

Routinely monitoring your patients throughout treatment may help to ensure they are on the appropriate dose that works for them.

	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

[a]Monitor periodically. Per physician discretion.

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

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

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

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

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:

- 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 MDS or AML.

Discontinue ZEJULA if MDS/AML is confirmed.

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

AML, acute myeloid leukemia; **MDS**, myelodysplastic syndrome.

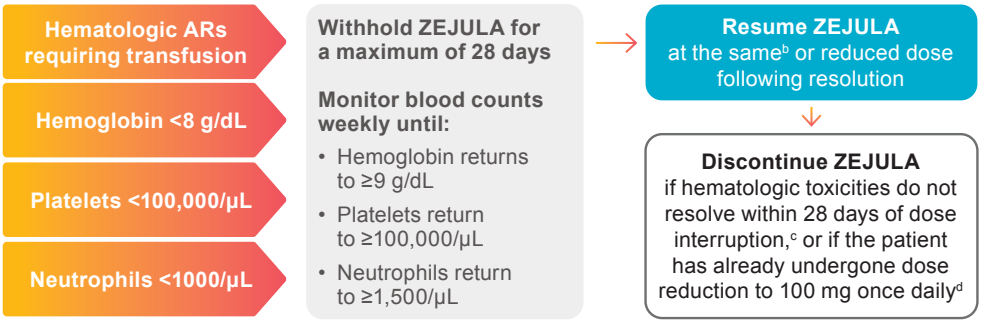
Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Dose adjustments can help manage select hematologic ARs[1]

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

Grade 3-4 hematologic ARs experienced during first-line maintenance treatment with ZEJULA include anemia, thrombocytopenia, neutropenia, and leukopenia.

In PRIMA, lower rates of select ARs were observed with an individualized starting dose.[a] In the HRD-positive population, compared with patients who received either the fixed starting dose or the individualized starting dose (n = 245), ZEJULA's individualized starting dose (n = 86) was observed to reduce rates of Grade 3-4 anemia from 31% to 22%; thrombocytopenia from 38% to 16%; and neutropenia from 17% to 13%.



[a]Exploratory subgroup analysis not powered to detect a significant treatment effect. Interpret results with caution.
[b]Resume at the same dose only for the first occurrence of thrombocytopenia if platelets are >75,000/µL.
[c]Refer the patient to a hematologist for further investigations.
[d]If myelodysplastic syndrome or acute myeloid leukemia (MDS/AML) is confirmed, discontinue ZEJULA.

AR, adverse reaction; **HRD**, homologous recombination deficient.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

1 DAILY DOSE

Zejula
niraparib
tablets 100/200/300 mg

In addition to dose modification, the strategies and interventions for select hematologic ARs on the following pages may help support your patients during treatment with ZEJULA.

This information does not cover all ARs for ZEJULA. Please refer to the accompanying full Prescribing Information for ZEJULA.

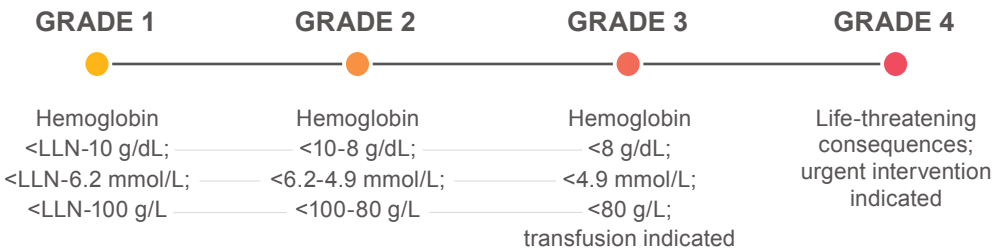
Other interventions may be necessary.
Please exercise independent clinical judgment.

AR, adverse reaction.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Anemia

Common Terminology Criteria for Adverse Events Grades[8]



Adapted from CTCAE Version 6.0.

For ZEJULA dosing recommendations, see page 10 of this brochure, as well as the ZEJULA Prescribing Information.

CTCAE, Common Terminology Criteria for Adverse Events; **LLN**, lower limit of normal.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Anemia (cont'd)

Practical tips from NCI for management of anemia in cancer patients[9]

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

Save energy and ask for help when needed – suggest that your patient choose the most important things to do each day, and when people offer to help, let them do so

Balance rest with activity – suggest that your patient take short naps during the day if they need to, but they may feel better if they exercise a little every day, too

Eat and drink well – your patient could talk with their doctor, nurse, or nutritionist to learn what foods and drinks are best for them. They may need to eat foods that are high in iron or protein

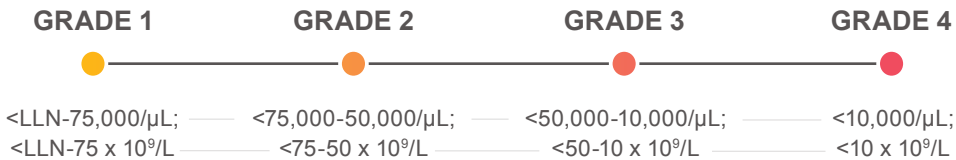
NCI, National Cancer Institute.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Thrombocytopenia/platelet count decreased

Common Terminology Criteria for Adverse Events Grades[8]

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



Adapted from CTCAE Version 6.0.

Based on the dosing recommendations from the ZEJULA Prescribing Information[1]:

- For patients with platelet count ≤10,000/uL, platelet transfusion should be considered

For ZEJULA dosing recommendations, see page 10 of this brochure, as well as the ZEJULA Prescribing Information.

CTCAE, Common Terminology Criteria for Adverse Events; **LLN**, lower limit of normal.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Thrombocytopenia/platelet count decreased (cont'd)

Practical tips from NCI for management of bleeding and bruising in cancer patients[10]

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

Avoid certain medicines – over-the-counter medicines that contain ibuprofen or aspirin can increase the risk of bleeding. Recommend that your patient speak to their doctor to find out which medicines they should avoid

Take extra care to prevent bleeding – your patient should brush their teeth gently and be extra careful when using sharp objects. Use lotion and lip balm to prevent dry, chapped skin and lips

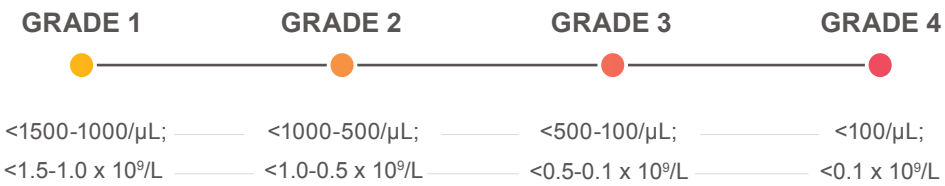
Care for bleeding or bruising – if your patient starts to bleed, they should press down firmly on the area with a clean cloth and keep pressing until the bleeding stops; if they bruise, put ice on the area

NCI, National Cancer Institute.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Neutropenia/neutrophil count decreased

Common Terminology Criteria for Adverse Events Grades[8]



Adapted from CTCAE Version 6.0.

For ZEJULA dosing recommendations, see page 10 of this brochure, as well as the ZEJULA Prescribing Information.

CTCAE, Common Terminology Criteria for Adverse Events.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Neutropenia/neutrophil count decreased (cont'd)

Practical tips from NCI for management of infection in cancer patients[11]

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

Wash hands often and well – recommend that your patient use soap and warm water to wash their hands, especially before eating

Stay extra clean – your patient should clean their teeth well; if they get a scrape or cut, they should clean it thoroughly

Avoid germs – inform your patient that they should try to stay away from people who are sick or have a cold. Avoid crowds and people who have just had a live vaccine. They should also follow food safety guidelines and make sure necessary foods are well cooked

NCI, National Cancer Institute.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Dose adjustments can help manage select non-hematologic ARs[1]

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

Grade 3-4 non-hematologic ARs experienced during first-line maintenance treatment with ZEJULA include nausea and vomiting, constipation, fatigue, insomnia, AST/ALT elevation, and hypertension.

In PRIMA, lower rates of certain non-hematologic ARs were observed with an individualized starting dose.[a] In the HRD-positive population, compared with patients who received either the fixed starting dose or the individualized starting dose (n = 245), ZEJULA's individualized starting dose (n = 86) was observed to reduce rates of Grade 1-4 constipation from 40% to 26%, vomiting from 23% to 16%, and nausea from 62% to 55%.

Recommended dose adjustments for patients experiencing non-hematologic ARs

CTCAE ≥Grade 3 AR that persists despite treatment management

- Withhold ZEJULA for a maximum of 28 days or until resolution of AR
- Resume ZEJULA at a reduced dose per recommended dose modifications for AR

CTCAE ≥Grade 3 treatment-related AR lasting more than 28 days while patient is administered ZEJULA 100 mg/day

Discontinue ZEJULA

[a]Exploratory subgroup analysis not powered to detect a significant treatment effect. Interpret results with caution.

ALT, alanine aminotransferase; **AR**, adverse reaction; **AST**, aspartate aminotransferase; **CTCAE**, Common Terminology Criteria for Adverse Events; **HRD**, homologous recombination deficient.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

In addition to dose modification, the strategies and interventions for select non-hematologic ARs on the following pages may help support your patients during treatment with ZEJULA.

This information does not cover all ARs for ZEJULA. Please refer to the full Prescribing Information for ZEJULA.

Other interventions may be necessary.
Please exercise independent clinical judgment.

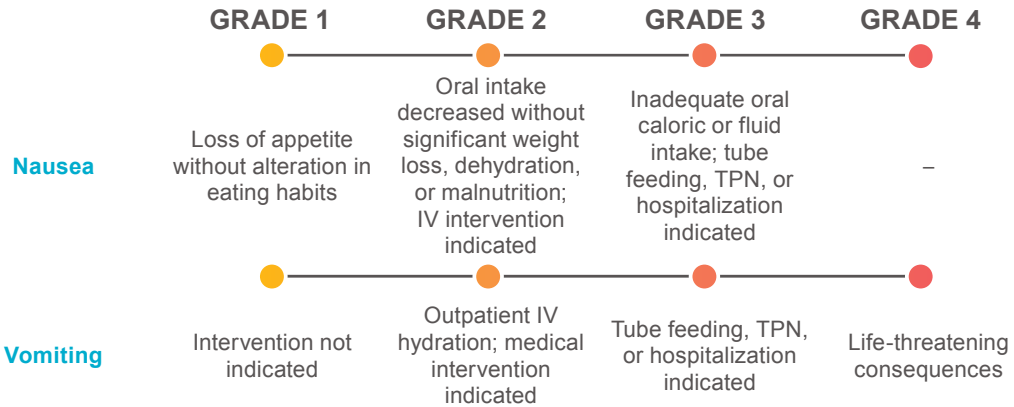
AR, adverse reaction.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Nausea and vomiting

Common Terminology Criteria for Adverse Events Grades[8]

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



Adapted from CTCAE Version 6.0.

For ZEJULA dosing recommendations, see page 18 of this brochure, as well as the ZEJULA Prescribing Information.

CTCAE, Common Terminology Criteria for Adverse Events; **IV**, intravenous; **TPN**, total parenteral nutrition.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Nausea and vomiting (cont'd)

Practical tips from NCI for management of nausea and vomiting in cancer patients

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

Take anti-nausea medicine as prescribed[12]

Drink plenty of water and fluids – drinking will help to prevent dehydration[12]

Avoid foods that could upset your stomach – greasy, fried, sweet, or spicy foods may aggravate the stomach. It may help to try cold foods that do not have a strong odor[12]

Be mindful on treatment day – It may help to eat a small snack before treatment, while other people find that it is better to avoid eating or drinking right before or after treatment[13]

Based on the Prescribing Information for ZEJULA: Taking ZEJULA at bedtime may help manage nausea[1]

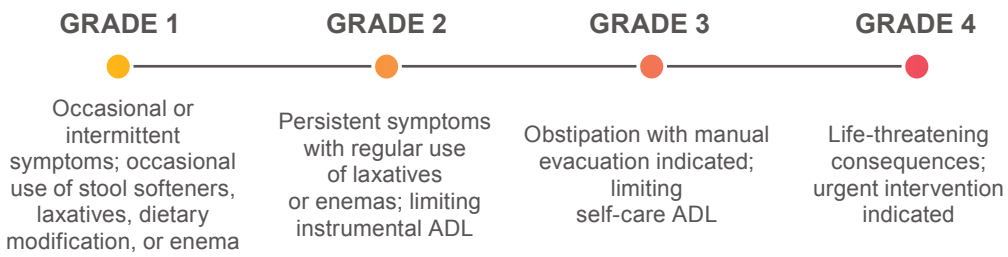
NCI, National Cancer Institute.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Constipation

Common Terminology Criteria for Adverse Events Grades[8]

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



Adapted from CTCAE Version 6.0.

For ZEJULA dosing recommendations, see page 18 of this brochure, as well as the ZEJULA Prescribing Information.

ADL, activities of daily living; **CTCAE**, Common Terminology Criteria for Adverse Events.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Constipation (cont'd)

Practical tips from NCI for management of constipation in cancer patients

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

Drink plenty of liquids – most people need to drink at least 8 glasses of liquid each day[13,14]

Drink hot liquids – some people find that drinking warm or hot liquids (such as coffee, tea, and soup) can help relieve constipation[13]

Try to be active every day – light exercise may help your patient feel better[14]

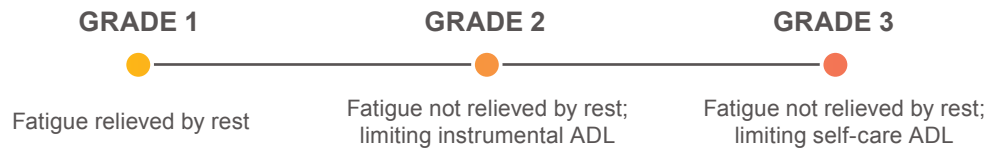
Keep a record of bowel movements – show to the doctor or nurse and talk about what is normal for them[13]

NCI, National Cancer Institute.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Fatigue

Common Terminology Criteria for Adverse Events Grades[8]



Adapted from CTCAE Version 6.0.

For ZEJULA dosing recommendations, see page 18 of this brochure, as well as the ZEJULA Prescribing Information.

ADL, activities of daily living; **CTCAE**, Common Terminology Criteria for Adverse Events.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Fatigue (cont'd)

Practical tips from NCI for management of fatigue in cancer patients[15]

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

Plan time to rest – if tired, your patient should take short naps of less than one hour during the day

Exercise and physical activity – exercise, including walking, may help your patient have more energy. The healthcare team can help them make an exercise plan

Eat and drink well – meeting with a nutritionist may help your patient learn more about foods and drinks that can increase energy levels

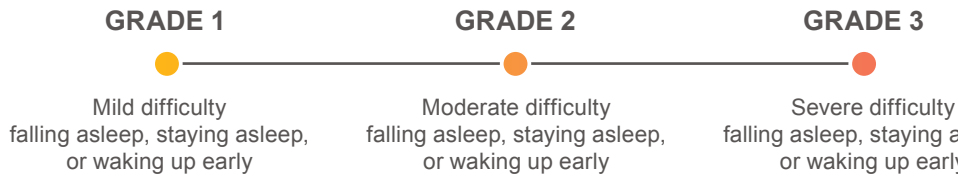
Meet with a specialist – it may help for your patient to meet with mental health therapists. Beneficial forms of therapy include physically based therapies and CBT

CBT, cognitive behavioral therapy; **NCI**, National Cancer Institute.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Insomnia

Common Terminology Criteria for Adverse Events Grades[8]



Adapted from CTCAE Version 6.0.

The NCI recommends treatment of secondary problems and sleep medicine, if necessary, for patients experiencing insomnia[16]

- Advise your patients to tell you of any problems that may be disturbing their sleep. Treatment of secondary problems, such as pain or other ARs, may help improve sleep
- Prescribe sleep medications, if necessary

For ZEJULA dosing recommendations, see page 18 of this brochure, as well as the ZEJULA Prescribing Information.

AR, adverse reaction; **CTCAE**, Common Terminology Criteria for Adverse Events; **NCI**, National Cancer Institute.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

Insomnia (cont'd)

Practical tips from NCI for management of insomnia in cancer patients

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

Meet with a specialist – trying CBT and relaxation therapy, in addition to strategies such as muscle relaxation, guided imagery, and self-hypnosis, may help your patient sleep[16]

Stay active during the day – recommend that your patient exercises regularly to help with sleep, but they shouldn't exercise within 3 hours of bedtime[17]

Set good bedtime habits – suggest that your patient goes to bed only when tired. Recommend they stop watching television or using electrical devices a couple of hours before going to bed and avoid large amounts of food or drink a few hours before bedtime[16]

Make their bed and bedroom comfortable – keep the room quiet, dark, and at a comfortable temperature. Dress in loose, soft clothing and use blankets to keep warm[17]

Avoid naps – sleeping during the day may stop them from feeling tired at bedtime[17]

CBT, cognitive behavioral therapy; **NCI**, National Cancer Institute.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

An established safety profile in 1L maintenance treatment of HRD-positive advanced ovarian cancer[1-3]

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

- **An individualized starting dose was observed to lower rates of select ARs while maintaining efficacy in an exploratory analysis[1,4,5,a,b]**
- **Select adverse events may be managed with dose interruption and/or modification[1]**
- **Monitoring complete blood counts, blood pressure, and heart rate helps identify the need to dose modify with ZEJULA[1]**

[a]Based on baseline bodyweight and platelet count.[1,4,5]
[b]Exploratory subgroup analysis, not powered to detect a statistically significant treatment effect. Interpret results with caution.

1L, first-line; **AR**, adverse reaction; **HRD**, homologous recombination deficient.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

The only once-daily oral PARPi monotherapy available for patients with HRD-positive advanced ovarian cancer[1,6,7]

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

ZEJULA PROVIDES A CONVENIENT, ONCE-DAILY ORAL TREATMENT THAT CAN BE TAKEN[1,a]:

With or without food

At home or on the go[b]

At any time of day or night[c]

[a]Routine monitoring of blood counts, blood pressure, and heart rate is required as part of treatment with ZEJULA.

[b]Tablets must be stored and dispensed in original container.

[c]ZEJULA should be taken at approximately the same time each day.

HRD, homologous recombination deficient; **PARPi**, poly (ADP-ribose) polymerase inhibitor.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

References

1. ZEJULA (niraparib). Prescribing information. GSK; 2025.
2. González-Martín A et al. *N Engl J Med.* 2019;381(25):2391-2402. doi:10.1056/NEJMoa1910962
3. Monk BJ et al. *Ann Oncol.* 2024;35(11):981-992. doi:10.1016/j.annonc.2024.08.2241
4. Mirza MR et al. *Cancer.* 2023;1-10. doi:10.1002/cncr.34706
5. Korach J et al. *Int J Gynecol Cancer.* 2020;30(suppl 4):A125-A126. doi:10.1136/ijgc-2020-ESGO.220
6. Lynparza (olaparib). Prescribing information. AstraZeneca Pharmaceuticals LP; 2025.
7. Rubraca (rucaparib). Prescribing information. pharmaand GmbH; 2025.
8. Common Terminology Criteria for Adverse Events (CTCAE) Version 6.0. National Cancer Institute (NCI). Accessed December 2, 2025. https://dctd.cancer.gov/research/ctep-trials/for-sites/adverse-events/ctcae-v6.pdf
9. Anemia: cancer treatment side effect. National Cancer Institute (NCI). Accessed December 2, 2025. https://www.cancer.gov/about-cancer/treatment/side-effects/anemia
10. Bleeding and bruising (thrombocytopenia) and cancer treatment. National Cancer Institute (NCI). Accessed December 2, 2025. https://www.cancer.gov/about-cancer/treatment/side-effects/bleeding-bruising

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

References (cont'd)

11. Infection and neutropenia during cancer treatment. National Cancer Institute (NCI). Accessed December 2, 2025. https://www.cancer.gov/about-cancer/treatment/side-effects/infection

12. Nausea and vomiting and cancer treatment. National Cancer Institute (NCI). Accessed December 2, 2025. https://www.cancer.gov/about-cancer/treatment/side-effects/nausea

13. Support for people with cancer. Eating hints: before, during, and after cancer treatment. National Cancer Institute (NCI). Accessed December 2, 2025. https://www.cancer.gov/publications/patient-education/eatinghints.pdf

14. Constipation and cancer treatment. National Cancer Institute (NCI). Accessed December 2, 2025. https://www.cancer.gov/about-cancer/treatment/side-effects/constipation

15. Cancer fatigue. National Cancer Institute (NCI). Accessed December 2, 2025. https://www.cancer.gov/about-cancer/treatment/side-effects/fatigue

16. Sleep problems in people with cancer. National Cancer Institute (NCI). Accessed December 2, 2025. https://www.cancer.gov/about-cancer/treatment/side-effects/sleep-disorders

17. Sleep disorders (PDQ®)–patient version. National Cancer Institute (NCI). Accessed December 2, 2025. https://www.cancer.gov/about-cancer/treatment/side-effects/sleep-disorders-pdq

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FOR PATIENTS WITH COMPLETE OR PARTIAL RESPONSE TO FIRST-LINE PLATINUM-BASED CHEMOTHERAPY[1]

1 DAILY DOSE

Zejula niraparib tablets 100/200/300 mg

ZEJULA: THE ONLY FDA-APPROVED PARPi WITH STATISTICALLY SIGNIFICANT PFS ACROSS HRD-POSITIVE ADVANCED OVARIAN CANCER[1,6,7,a,b]

[a]Defined by either a deleterious *BRCA* mutation, and/or genomic instability.[1]

[b]PRIMA: A double-blind, placebo-controlled phase 3 trial of patients with newly diagnosed advanced ovarian cancer who were randomized 2:1 to ZEJULA or placebo. PFS was the primary endpoint evaluated by BICR, per RECIST v1.1, in the primary analysis (13.8-month follow-up). Homologous recombination status was a stratification factor in PRIMA, and hierarchical testing was used to control for overall type 1 error. In the HRD-positive population (n = 373): mPFS with ZEJULA was 21.9 months (95% CI, 19.3-NE) vs 10.4 months (95% CI, 8.1-12.1) with placebo; HR, 0.43 (95% CI, 0.31-0.59, *P*<0.0001).[1,2]

Indication

ZEJULA (niraparib) 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) has occurred in patients exposed to ZEJULA and some cases were fatal. Monitor patients for hematological toxicity and discontinue if MDS/AML is confirmed.

Please see Important Safety Information on pages 2-3, as well as the accompanying full Prescribing Information.

BICR, blinded independent central review; ***BRCA***, breast cancer susceptibility gene; **CI**, confidence interval; **FDA**, US Food and Drug Administration; **HR**, hazard ratio; **HRD**, homologous recombination deficient; **mPFS**, median PFS; **NE**, not estimable; **PARPi**, poly (ADP-ribose) polymerase inhibitor; **PFS**, progression-free survival; **RECIST**, Response Evaluation Criteria in Solid Tumors.

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