FOR 1L MAINTENANCE OF ADULT PATIENTS WITH PLATINUM-RESPONSIVE ADVANCED OVARIAN CANCER¹





Managing select adverse reactions for ZEJULA in first-line maintenance

Indication

ZEJULA (niraparib) tablets are 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 first-line platinum-based chemotherapy.

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

1L, first-line.



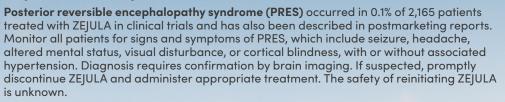
Important Safety Information

Myelodysplastic syndrome/acute myeloid leukemia (MDS/AML), including cases with a fatal outcome, have been reported in patients who received ZEJULA. In PRIMA, MDS/AML occurred in 6 out of 484 (1.2%) patients treated with ZEJULA, and in 3 out of 244 (1.2%) patients treated with placebo. The duration of therapy with ZEJULA in patients who developed secondary MDS/cancer therapy-related AML varied from 3.7 months to 2.5 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 hypertensive crisis 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.

Important Safety Information (cont'd)





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 Advanced Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of all patients who received ZEJULA in PRIMA were thrombocytopenia (66%), anemia (64%), nausea (57%), fatigue (51%), neutropenia (42%), constipation (40%), musculoskeletal pain (39%), leukopenia (28%), headache (26%), insomnia (25%), vomiting (22%), dyspnea (22%), decreased appetite (19%), dizziness (19%), cough (18%), hypertension (18%), AST/ALT elevation (14%), and acute kidney injury (12%).

Common lab abnormalities (Grades 1–4) in ≥25% of all patients who received ZEJULA in PRIMA included: decreased hemoglobin (87%), decreased platelets (74%), decreased leukocytes (71%), increased glucose (66%), decreased neutrophils (66%), decreased lymphocytes (51%), increased alkaline phosphatase (46%), increased creatinine (40%), decreased magnesium (36%), increased AST (35%), and increased ALT (29%).

Please see accompanying <u>Prescribing Information for ZEJULA tablets</u>.

ALT, alanine aminotransferase; AST, aspartate aminotransferase.

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Please see Important Safety Information on pages 2–3, as well as the accompanying full <u>Prescribing Information</u>.

An individualized starting dose in 1LM, giving your patients a tailored dose from the start¹

ZEJULA is the only once-daily oral PARP inhibitor monotherapy approved for eligible 1L platinum responders with advanced ovarian cancer.¹⁻⁵



Patients should start treatment no later than 12 weeks after their most recent platinum-containing regimen¹

If baseline weight <170 lbs or platelets <150,000/µL

200 mg/day

First dose reduction: 100 mg/day

Second dose reduction: discontinue

If baseline weight ≥170 lbs and platelets ≥150,000/µL

300 mg/day

First dose reduction: 200 mg/day Second dose reduction:

100 mg/day

reduction: discontinue

Third dose

For patients with moderate hepatic impairment, reduce the starting dosage of ZEJULA to 200 mg once daily. Monitor periodically. Per physician discretion.1

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

The PRIMA trial¹

PRIMA, a randomized, double-blind, placebo-controlled phase 3 trial, evaluated the safety and efficacy of ZEJULA in women (N=733) with newly diagnosed advanced ovarian cancer following CR or PR to 1L platinum-based chemotherapy.¹⁴ The primary endpoint was PFS in patients who had HRd tumors and in those in the overall population.⁴ Overall population (N=733): median PFS of 13.8 months for ZEJULA vs 8.2 months for placebo (HR: 0.62; 95% Cl: 0.50-0.76; P<0.0001), HRd population (n=373): median PFS of 21.9 months for ZEJULA vs 10.4 months for placebo (HR: 0.43; 95% CI: 0.31-0.59; P<0.0001).1

ZEJULA offers an individualized starting dose that was shown to lower rates of select ARs while maintaining efficacy^{1,5,6}

PRIMA prospectively evaluated the safety and efficacy of an individualized starting dose (n=169) of either 200 mg or 300 mg, selected based on baseline weight and platelet count, as well as a fixed starting dose (n=315) of 300 mg.^{1,5} In patients taking an individualized starting <u>dose, comparable efficacy</u> was observed as measured by the HR for PFS. Overall population (n=258): HR: 0.68 (95% CI: 0.48-0.97); HRd population (n=130): HR: 0.39 (95% CI: 0.22-0.72); BRCAm population (n=53): HR: 0.29 (95% CI: 0.13-0.67).6 These prespecified subgroup analyses were exploratory and not powered to detect a statistically significant treatment effect. Interpret results with caution.

Compared with the overall population, ZEJULA's individualized starting dose was shown to reduce rates of Grade 3-4 anemia from 31% to 23%; thrombocytopenia from 39% to 21%; and neutropenia from 21% to 15% in patients with advanced ovarian cancer.^{1,5} In PRIMA, patients in the overall and individualized populations experienced the same rates of Grade 3-4 leukopenia.1

1L, first-line; 1LM, first-line maintenance; AR, adverse reaction; BRCAm, breast cancer susceptibility gene mutation; CI, confidence interval; CR, complete response; HR, hazard ratio; HRd, homologous recombination deficient; PARP, poly (ADP-ribose) polymerase; PFS, progression-free survival; PR, partial response.

Monitoring complete blood counts, blood pressure, and heart rate helps identify the need to dose modify¹

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

Blood counts REST OF YEAR ONCE A WEEK ONCE A MONTH ONCE A WORLD ONCE A WORLD ONCE EVERY 2-3 MONTHS*

Blood pressure and heart rate

ONCE A WEEK	ONCE A MONTH	ONCE EVERY 2-3 MONTHS*
1 ST AND 2 ND MONTHS	REST OF YEAR	AFTER YEAR 1:

Symptoms of low blood counts may indicate serious bone marrow problems¹



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

Fever

· Feeling tired

Shortness of breath

Weight loss

Blood in urine or stool

Frequent Infections

Bruising or bleeding easily

This may be a sign of hematological toxicity or MDS or AML.

ZEJULA should be permanently discontinued if a diagnosis of MDS or AML is confirmed.¹

ZEJULA may cause other side effects. Please refer to the Important Safety Information on pages 2–3 as well as the accompanying full <u>Prescribing Information</u>.

AML, acute myeloid leukemia; MDS, myelodysplastic syndrome.

^{*}Monitor periodically. Per physician discretion.



With ZEJULA, your patients can plan their treatment around their life and not their life around their treatment^{1*}



Convenient, one-tablet, once-daily dosing¹



At home or on the go*†

[†]Tablets must be stored and dispensed in original container.¹



At any time of day or night18

⁵ZEJULA can be taken any time of day, with or without food. Patients should be encouraged to take ZEJULA at approximately the same time each day. Bedtime administration may be a potential method for managing nausea.



A therapy for which no specific drug-drug interactions have been reported^{1‡}

[‡]No clinical drug interaction studies have been performed with ZEJULA.

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

Please see Important Safety Information on pages 2–3, as well as the accompanying full <u>Prescribing Information</u>.

ZEJULA: Recommended starting dose in select special populations



Reduce the starting dosage of ZEJULA to 200 mg once daily

For moderate hepatic impairment



Moderate:

Total bilirubin ≥1.5–3x ULN and any AST level

Monitor patients for hematologic toxicity and reduce the dose further, if needed.

No dose adjustment necessary

For mild/moderate renal impairment[¶]



Mild: CLcr: 60-89 mL/min

Moderate: CLcr: 30–59 mL/min

For mild hepatic impairment



Mild:

<1.5x ULN total bilirubin and any AST level or bilirubin

S ULN and AST > ULN

For age

≥65 years

for patients with severe hepatic impairment (total bilirub

The recommended starting dose of ZEJULA has not been established for patients with severe hepatic impairment (total bilirubin >3.0x ULN and any AST level).

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

AST, aspartate transaminase; CLcr, creatinine clearance; ULN, upper limit of normal.

Routine monitoring and dose adjustments can help manage hematologic ARs¹

Grade 3-4 hematologic ARs experienced during first-line maintenance treatment with ZEJULA include anemia, thrombocytopenia, neutropenia, and leukopenia.¹

An individualized starting dose for ZEJULA in first-line maintenance was shown to lower rates of select ARs. Compared with the overall population (n=484), ZEJULA's individualized starting dose (n=169) was shown to reduce rates of Grade 3-4 anemia from 31% to 23%; thrombocytopenia from 39% to 21%; and neutropenia from 21% to 15% in patients with advanced ovarian cancer.^{1,5} In PRIMA, patients in the overall and individualized populations experienced the same rates of Grade 3-4 leukopenia.1

Hematologic ARs requiring transfusion

Hemoglobin <8 g/dL

Platelets <100,000/µL

Neutrophils <1000/μL

Withhold ZEIULA for a maximum of 28 days

Monitor blood counts weekly until:

- Hemoglobin returns to ≥9 g/dL
- Platelets return to ≥100,000/µL
- Neutrophils return to ≥1,500/μL

Resume ZEJULA

at the same* or reduced dose following resolution



Discontinue ZEJULA

if hematologic toxicities do not resolve within 28 days of dose interruption,† or if the patient has already undergone dose reduction to 100 mg once daily[‡]





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

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 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 <u>Prescribing Information for</u> ZEIULA tablets.

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

Anemia

Common Terminology Criteria for Adverse Events Grades⁷

Practical tips from NCI for management of anemia in cancer patients⁸





Adapted from CTCAE Version 5.0.



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 takes 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 – patients 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

CTCAE, Common Terminology Criteria for Adverse Events; LLN, lower limit of normal; NCI, National Cancer Institute.

Please see dose modifications for hematologic adverse reactions on page 12, as well as table 3 on page 4 in the accompanying full <u>Prescribing Information</u>.

Thrombocytopenia/platelet count decreased

Common Terminology Criteria for Adverse Events Grades⁷

Practical tips from NCI for management of bleeding and bruising in cancer patients⁹





Adapted from CTCAE Version 5.0.

Based on the Prescribing Information for ZEJULA1:

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



Avoid certain medicines – over-the-counter medicines that contain ibuprofen or aspirin can increase the risk of bleeding. Recommend that your patient speaks 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, and, if they bruise, put ice on the area

CTCAE, Common Terminology Criteria for Adverse Events; LLN, lower limit of normal; NCI, National Cancer Institute.

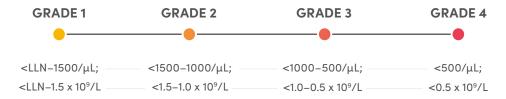
Please see table 3 on page 4 in the accompanying full <u>Prescribing Information</u> for ZEJULA related to dose modifications for hematologic adverse reactions.

Neutropenia/neutrophil count decreased

Common Terminology Criteria for Adverse Events Grades⁷

Practical tips from NCI for management of infection in cancer patients¹⁰





Adapted from CTCAE Version 5.0.



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



Stay extra clean – your patient should clean their teeth well and, 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

CTCAE, Common Terminology Criteria for Adverse Events; LLN, lower limit of normal; NCI, National Cancer Institute.

Please see table 3 on page 4 in the accompanying full <u>Prescribing Information</u> for ZEJULA related to dose modifications for hematologic adverse reactions.

Routine monitoring and dose adjustments can help manage non-hematologic ARs¹

Grade 3–4 non-hematologic ARs experienced during first-line maintenance treatment with ZEJULA include nausea and vomiting, constipation, fatigue, insomnia, AST/ALT, and hypertension.¹

An individualized starting dose with ZEJULA was shown to lower rates of certain non-hematologic ARs in first-line maintenance. Compared with the overall population (n=484), ZEJULA's individualized starting dose (n=169) was shown to reduce rates of Grade 1–4 constipation from 40% to 31% and vomiting from 22% to 17% in patients with advanced ovarian cancer.¹

Recommended dose adjustments for patients experiencing non-hematologic ARs¹

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

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 <u>Prescribing Information for ZEJULA tablets</u>.

Other interventions may be necessary.

Please exercise independent clinical judgment.

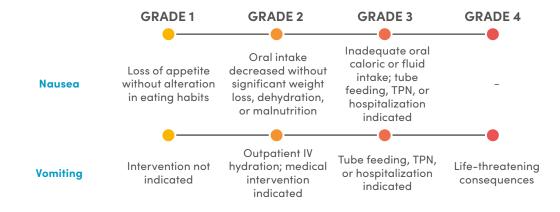
ALT, alanine aminotransferase; AR, adverse reaction; AST, aspartate aminotransfera CTCAE, Common Terminology Criteria for Adverse Events.

Nausea and vomiting

Common Terminology Criteria for Adverse Events Grades⁷

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





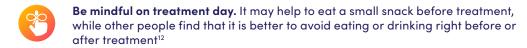
Adapted from CTCAE Version 5.0.

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











CTCAE, Common Terminology Criteria for Adverse Events; IV, intravenous; NCI, National Cancer Institute; TPN, total parenteral nutrition.

Please see dose modifications for non-hematologic adverse reactions on page 20, as well as table 2 on page 3 of the accompanying full <u>Prescribing Information</u>.

Constipation

Common Terminology Criteria for Adverse Events Grades⁷

Practical tips from NCI for management of constipation in cancer patients





Adapted from CTCAE Version 5.0.



Eat high-fiber foods – these include whole grain breads and cereals, dried fruits, and cooked dried beans or peas¹²



Drink plenty of liquids – most people need to drink at least 8 glasses of liquid each day^{12,13}

Drink hot liquids – some people find that drinking warm or hot liquids (such as coffee, tea, and soup) can help relieve constipation¹²



Try to be active every day – light exercise, up to 30 minutes each day, may help your patient feel better¹³



Keep a record of bowel movements – to show to the doctor or nurse and talk about what is normal for them¹²

ADL, activities of daily living; CTCAE, Common Terminology Criteria for Adverse Events; NCI, National Cancer Institute.

Please see table 2 on page 3 in the accompanying full <u>Prescribing Information</u> for ZEJULA related to dose modifications for non-hematologic adverse reactions.

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

Fatigue

Common Terminology Criteria for Adverse Events Grades⁷

Practical tips from NCI for management of fatigue in cancer patients





Adapted from CTCAE Version 5.0.



Balance rest and activity – patients should choose activities that are relaxing, such as listening to music, reading, or meditating¹⁴



Try to exercise moderately for 3 to 5 hours a week – choosing a type of exercise that your patient enjoys may help them stick to an exercise plan. The healthcare team can help them plan the best time and place for exercise, and how often¹5



Eat and drink well – meeting with a nutritionist may help your patient learn more about foods and drinks that can increase energy levels¹⁴



Meet with a specialist – it may help for patients to meet with a counselor, psychologist, or psychiatrist. Beneficial forms of therapy include physically based therapies and CBT for insomnia^{14,15}

ADL, activities of daily living; CBT, cognitive behavioral therapy; CTCAE, Common Terminology Criteria for Adverse Events; NCI, National Cancer Institute.

Please see table 2 on page 3 in the accompanying full <u>Prescribing Information</u> for ZEJULA related to dose modifications for non-hematologic adverse reactions.

Insomnia

Common Terminology Criteria for Adverse Events Grades⁷

Practical tips from NCI for management of insomnia in cancer patients





Adapted from CTCAE Version 5.0.

The NCI recommends treatment of secondary problems and sleep medicine, if necessary, for patients experiencing insomnia¹⁶

- 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



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 sleep¹⁶



Stay active during the day – recommend that your patient exercises regularly to help with sleep, but they shouldn't exercise within 3 hours of bedtime¹⁷



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 bedtime¹⁶

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 warm¹⁷

Avoid naps – sleeping during the day may stop them from feeling tired at bedtime¹⁷

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

Please see table 2 on page 3 in the accompanying full <u>Prescribing Information</u> for ZEJULA related to dose modifications for non-hematologic adverse reactions.

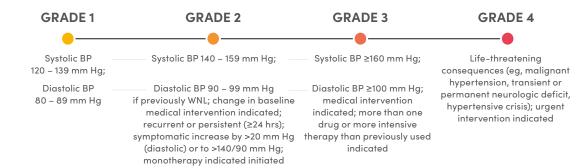
Please see Important Safety Information on pages 2–3, as well as the accompanying full Prescribing Information.

Hypertension

Common Terminology Criteria for Adverse Events Grades⁷

Practical tips from ASCO's patient education program for management of hypertension in cancer patients¹⁸





Criteria for adult hypertension adapted from CTCAE Version 5.0.

Based on the Prescribing Information for ZEJULA1:

- Monitor blood pressure and heart rate at least weekly for the first 2 months, then monthly for the first year of treatment and periodically thereafter
- · Advise patients to contact their healthcare provider if blood pressure is elevated

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



Review your patient's medical record – verify if your patient takes any blood pressure or heart medications, and recommend that your patient tells their primary care provider that they are in treatment for cancer



Work with your patient's cardiologist or primary care provider – reduce your patient's cardiovascular risks before, during, and after treatment. If your patient already has high blood pressure or heart disease, adjustment of medicine may be needed during treatment for cancer



Lifestyle changes – suggest lifestyle changes that may lower blood pressure and stress. These may include quitting smoking, eating a hearthealthy diet, and getting regular physical activity. Recommend that your patient speaks to their doctor before starting an exercise program

ASCO, American Society of Clinical Oncology; BP, blood pressure; CTCAE, Common Terminology Criteria for Adverse Events; WNL, within normal limits.

Please see dose modifications for non-hematologic adverse reactions in table 2 on page 3 in the accompanying full <u>Prescribing Information</u>.



An established safety and tolerability profile^{1,4*}



Individualized starting dose that was shown to lower rates of select ARs^{1,5†}



Side effects of ZEJULA may be managed with dose interruption and modification¹



Convenient, one-tablet, once-daily, oral monotherapy which can be taken any time of day, with or without food.¹ ZEJULA should be taken at approximately the same time each day¹



Monitoring complete blood counts, blood pressure, and heart rate helps identify the need to **dose modify with ZEJULA**¹

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

^{*}At the time of primary analysis.

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

References

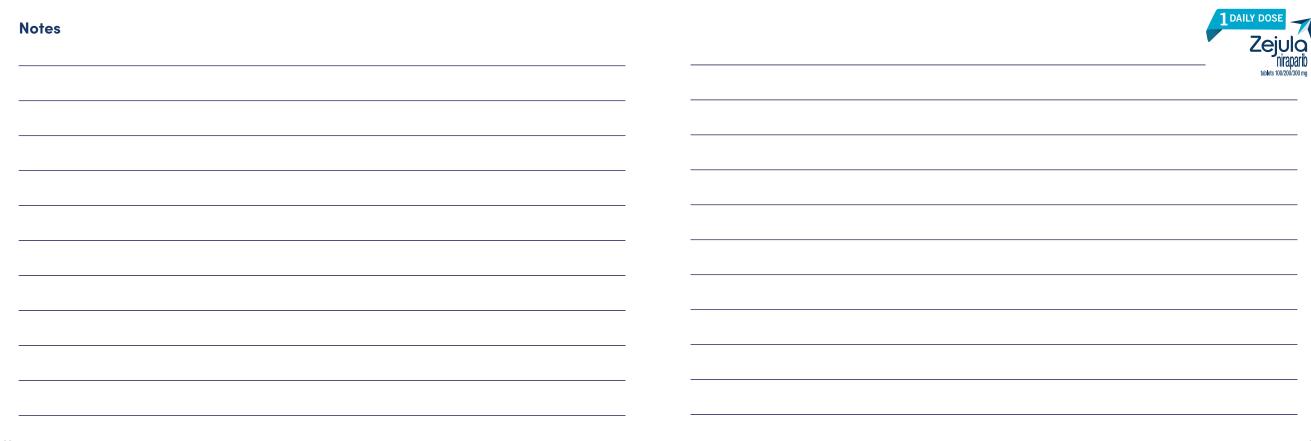
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Please see Important Safety Information on pages 2-3, as well as the accompanying full <u>Prescribing Information</u>.

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FOR 1L MAINTENANCE OF ADULT PATIENTS WITH PLATINUM-RESPONSIVE ADVANCED OVARIAN CANCER¹





A once-daily oral PARP inhibitor monotherapy with an established safety and tolerability profile

Indication

ZEJULA (niraparib) tablets are 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 first-line platinum-based chemotherapy.

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

1L, first-line; PARP, poly (ADP-ribose) polymerase.

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