1 DAILY DOSE

Zejula
niraparib
tablets 100/200/300 mg

# INTRODUCING ZEJULA TABLETS: SAME MAINTENANCE TREATMENT, NEW DOSAGE FORM[1,2]

## Available in August as one tablet, once-daily[2]

**ZEJULA tablets and capsules are bioequivalent.*[3] No interruption to your patients' therapy with ZEJULA should be needed due to change in formulation.[1-2]**

*In a pharmacokinetic study with 108 patients with solid tumors, under fasting conditions, one 300 mg tablet was bioequivalent to three 100 mg capsules, based on plasma concentration of niraparib.[3]

ZEJULA (niraparib) capsules 100 mg and tablets 100 mg/200 mg/300 mg are indicated[1,2]:

- 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
- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA

## Important Safety Information for ZEJULA Capsules and Tablets

**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 additional Important Safety Information on pages 2–3 and the accompanying Prescribing Information for ZEJULA capsules and tablets.**

## Important Safety Information (continued)

**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. In NOVA, of patients within the g*BRCA*mut cohort, MDS/AML occurred in 10 out of 136 (7%) patients treated with ZEJULA and in 2 out of 65 (3%) patients treated with placebo. The duration of therapy with ZEJULA in patients who developed secondary MDS/cancer therapy-related AML varied from 3.6 months to 5.9 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 and 29%, 25%, and 20% of patients receiving ZEJULA in NOVA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 4%, 2%, and 2% of patients in PRIMA and 3%, 1%, and 2% of patients in NOVA. 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. Grade 3-4 hypertension occurred in 9% of patients receiving ZEJULA vs 2% of patients receiving placebo in NOVA, with discontinuation occurring in <1% of patients. 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.

**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.



## 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.

**Allergic reactions to FD&C Yellow No. 5 (tartrazine):** ZEJULA capsules contain FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

**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%).

**Maintenance Recurrent Germline *BRCA*-mutated Ovarian Cancer**

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received ZEJULA in NOVA g*BRCA*mut Cohort were nausea (77%), thrombocytopenia (71%), fatigue (61%), anemia (52%), vomiting (40%), constipation (38%), headache (35%), neutropenia (31%), decreased appetite (22%), hypertension (21%), insomnia (18%), dizziness (18%), dyspnea (17%), dyspepsia (17%), back pain (16%), cough (16%), nasopharyngitis (13%), dry mouth (13%), dysgeusia (13%), urinary tract infection (11%), rash (10%), and anxiety (10%).

Common lab abnormalities (Grades 1-4) in ≥25% of patients who received ZEJULA in NOVA g*BRCA*mut Cohort included: decrease in hemoglobin (85%), decrease in platelet count (81%), decrease in white blood cell count (71%), decrease in absolute neutrophil count (56%), increase in AST (35%), and increase in ALT (25%).

**Please see full Prescribing Information for ZEJULA capsules and tablets.**

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

**ALT**, alanine aminotransferase; **AML**, acute myeloid leukemia; **AST**, aspartate aminotransferase; **g*BRCA*mut**, germline *BRCA* mutated; **MDS**, myelodysplastic syndrome.

# The new ZEJULA tablet offers a once-daily dosing with fewer pills[1,2]

**ZEJULA tablets may reduce pill burden: patients will take 1 tablet at their prescribed dose compared to one or more capsules[1,2]**

1 tablet once-daily, regardless of strength

Tablets are film-coated and have a reduced size compared to capsules[3]

Tablets ingredients:

- Contain less lactose than capsules
- Do not contain gelatin and tartrazine (a potential allergen), which may allow for use in patients with related dietary restrictions

Every patient needs a new prescription when switching from ZEJULA capsules to tablets.

**Please see additional Important Safety Information on pages 2–3 and the accompanying Prescribing Information for ZEJULA capsules and tablets.**

# The same convenient once-daily dosing – now in tablet form[1,2]

## Now, your patients will take one tablet, once-daily, regardless of the strength[2]

| Current Capsules[1] (actual size) | NEW ONCE-DAILY Tablet[2] (actual size) |
|---|---|
| 100 mg + 100 mg + 100 mg | 300 mg |
| 100 mg + 100 mg | 200 mg |
| 100 mg | 100 mg |

| | |
|---|---|
| Contain lactose (254.5 mg in each capsule) | Contain **less lactose** (34.7 mg in each tablet) |
| Gelatin coating on capsules | **Film-coated tablet** |
| Contain tartrazine (E102) - a potential allergen | **Does not contain tartrazine** |

| **Current Capsules You have been prescribing:** | **Tablets Please prescribe:** |
|---|---|
| **30-count capsule bottle** NDC 69656-0103-30 | **300-mg tablet** (30-count bottle) NDC 0173-0915-13 |
| | **200-mg tablet** (30-count bottle) NDC 0173-0912-13 |
| | **100-mg tablet** (30-count bottle) NDC 0173-0909-13 |

## Important Safety Information (continued)

### First-line Maintenance Advanced Ovarian Cancer

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%).

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

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

# New dosage form, same treatment schedule[1,2]

Can be taken at any time of day. Patients should take their dose at approximately the same time each day*

Should be swallowed whole, do not crush, chew, or split tablet

May be taken with or without food

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

No specific drug-drug interactions have been reported with ZEJULA†

*Bedtime administration may be a potential method for managing nausea.[1,2] †No clinical drug interaction studies have been performed with ZEJULA.[1,2]

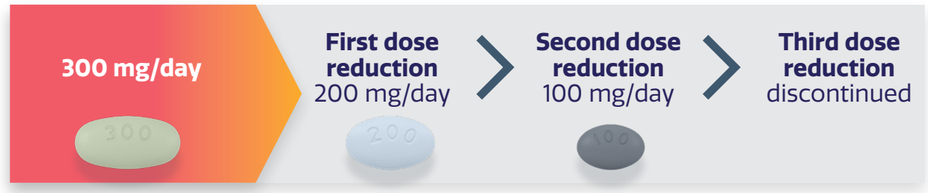
**Please see additional Important Safety Information on pages 2–3 and the accompanying Prescribing Information for ZEJULA capsules and tablets.**

# The same individualized starting dose of ZEJULA for patients receiving first-line maintenance therapy[1,2]

## Giving your patients a tailored dose from the start

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


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




Tablet images shown are actual size.

For patients with moderate hepatic impairment, reduce the starting dosage of ZEJULA to 200 mg once daily. Monitor patients for hematologic toxicity and reduce the dose further, if needed.

**For the maintenance therapy of patients with recurrent germline *BRCA*-mutated ovarian cancer, the recommended dosage is 300 mg/day.**

## Important Safety Information (continued)

### 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%).

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

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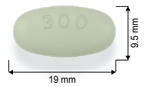
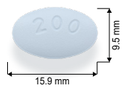
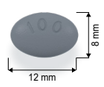
# What your patient can expect to receive

ZEJULA is switching from capsules to tablets[2]:

- ZEJULA tablets will be available in **3 different strengths**: 300 mg, 200 mg, and 100 mg
  - 300 mg, 200 mg, and 100 mg tablets will have different colors, debossed strengths on one side, and "ZEJULA" on the other.[3]

| | 300 mg | 200 mg | 100 mg |
|---|---|---|---|
| **Strengths on one side** |   |   |   |
| **ZEJULA on the other side** |   |   |   |

Tablet images shown are actual size.

- The recommended once-daily dosage of ZEJULA also remains the same. Now, your patient only needs to take **one tablet once-daily, regardless of the strength**[1,2]

## Important Safety Information (continued)

**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. In NOVA, of patients within the g*BRCA*mut cohort, MDS/AML occurred in 10 out of 136 (7%) patients treated with ZEJULA and in 2 out of 65 (3%) patients treated with placebo. The duration of therapy with ZEJULA in patients who developed secondary MDS/cancer therapy-related AML varied from 3.6 months to 5.9 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.



# ZEJULA tablet: same medication, new dosage form and new bottle[1,2]

## ZEJULA tablets contain the same active ingredients with the same expected efficacy[1,2]

ZEJULA tablets have been demonstrated to be bioequivalent and interchangeable[1–3]:

- 100-mg tablet has the **same** amount of niraparib as the 100-mg capsule
- 200-mg tablet has **twice** the amount of niraparib as the 100-mg capsules
- 300-mg tablet has **three** times the amount of niraparib as the 100-mg capsules
- In a pharmacokinetic study,* ZEJULA tablet formulation (300 mg) was shown to be bioequivalent to the marketed capsule formulation (3 x 100 mg)[3]

*In a pharmacokinetic study with 108 patients with solid tumors, under fasting conditions, one 300-mg tablet was bioequivalent to three 100-mg capsules, based on plasma concentration of niraparib.[3]

**ZEJULA will now come in a round bottle. Tablets must be stored and dispensed in original bottle.**

**Every patient needs a new prescription when switching from ZEJULA capsules to tablets.**

**Please see additional Important Safety Information on pages 2–3 and the accompanying Prescribing Information for ZEJULA capsules and tablets.**

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

# Planning for a smooth transition from capsules to tablets

## When tablets are available

- Specialty distributors will begin shipping tablets exclusively near the beginning of August
- New prescriptions will need to be written for ZEJULA tablets

**No interruption to your patients' therapy with ZEJULA should be needed due to change in formulation**

**ZEJULA Free Trial and Dose Modification Program**

Available for **new patients** or **patients who require mid-cycle dose changes** of their current tablet strength.

All ZEJULA Free Trial and Dose Modification Program prescriptions will be filled by the PharmaCord mail order pharmacy.

If future prescriptions are needed, they must be submitted to the patient's designated specialty or in-office dispensing pharmacy and are subject to review and approval by the patient's payer.

Future prescriptions are not required to participate in the ZEJULA Free Trial and Dose Modification Program.

Free Trial and Dose Modification Program launches in August. To enroll a patient, please visit www.ZEJULAHCP.com*

*For full terms and conditions.

## 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.



# Help your eligible patients get started on ZEJULA tablets

## ZEJULA patient support

**In-person or Virtual Sample Ordering**

**Sample Program***

**In-person or virtual sample ordering options are available,** talk to your GSK representative†‡ or request a sample online on your own time by registering at www.gsksamples.com§

**Patients Can Save on ZEJULA**

Pay as little as $0

The **ZEJULA Co-Pay Program** helps eligible commercially insured patients with their out-of-pocket costs for ZEJULA up to $26,000 for 12 months. Eligibility for the ZEJULA Co-Pay Program must be determined by the GSK Co-Pay Program. Eligibility restrictions and program maximums apply. Visit www.togetherwithgskoncology.com for complete Program Terms and Conditions.

GSK Together with GSK Oncology

## One source for GSK access and reimbursement services

*Samples are only for new patients to assess ZEJULA for tolerability. Before providing a patient with samples, first do a health benefit check to assess their prescription coverage. If patient assistance is required, samples are not appropriate. This will help ensure continued coverage or determine if patient assistance is required. All healthcare providers are eligible to receive saving offers, but not all are eligible to receive ZEJULA samples. A sample order for a patient should not exceed one 30-count bottle of ZEJULA 200-mg or 300-mg tablets. Samples are not for sale, trade, or reimbursement; therefore, samples cannot be billed or resold. †A remote signature through Veeva by the licensed healthcare provider is required before the meeting with a GSK representative ends. Once the signature is obtained, sample orders cannot be changed or cancelled. The signed sample request is restricted to only ZEJULA samples; any promotional material items are not available. ‡Sample Request Forms can now be completed electronically via QSign. Completed Sample Request Forms need to be signed and dated. Once an order is submitted, it cannot be cancelled. §ZEJULA Samples Program on GSKPro limits quantities from all sources to a total of 4 orders of 1 bottle per quarter.

1 DAILY DOSE

Zejula niraparib tablets 100/200/300 mg

**Please see additional Important Safety Information on pages 2–3 and the accompanying Prescribing Information for ZEJULA capsules and tablets.**

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**References:**

**1.** ZEJULA capsules. Prescribing Information. GSK; 2022. **2.** ZEJULA tablets. Prescribing Information. GSK; 2023.
**3.** Data on file. GSK.



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File name: Tablet HCP Education Brochure