

Zejula® (niraparib) – New formulation approval

- On April 26, 2023, the <u>FDA approved</u> GSK's <u>Zejula (niraparib)</u> tablets, for the 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
 - Deleterious or suspected deleterious germline BRCA-mutated (gBRCAmut) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- Zejula was previously approved as a <u>100 mg oral capsule</u>. The new oral tablet formulation will be available in a 100 mg, 200 mg, and 300 mg strength.
- For first-line maintenance treatment of advanced ovarian cancer, the recommended dose of Zejula is:
 - 200 mg taken orally once daily for patients weighing < 77 kg (< 170 lbs) OR with a platelet count of < 150,000/mcL
 - 300 mg taken orally once daily for patients weighing ≥ 77 kg (≥ 170 lbs) AND who have a platelet count ≥ 150,000/mcL
 - Patients should start treatment with Zejula no later than 12 weeks after their most recent platinum-containing regimen.
- For maintenance treatment of recurrent germline *BRCA*-mutated ovarian cancer, the recommended dose of Zejula is 300 mg taken orally once daily. Patients should start treatment with Zejula no later than 8 weeks after their most recent platinum-containing regimen.
- GSK's launch plans for Zejula tablets are pending.



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