Background: Niraparib (Zejula®) is an oral poly (adenosine diphosphate [ADP]–ribose) polymerase (PARP) 1/2 inhibitor that has demonstrated efficacy in patients with platinum-sensitive, recurrent ovarian cancer. Nausea, thrombocytopenia, and fatigue were commonly occurring adverse events (AEs) in the phase 3 clinical trial in which patients were started at 300 mg daily dose of niraparib. After dose adjustments in this trial, a daily dose of 200 mg was the most commonly administered dose. This analysis provides a description of AEs among patients receiving an initial dose of 200 mg niraparib.

Methods: In a retrospective observational patient study, 53 randomly selected study-qualified physicians from a national database (61% of qualified physicians screened) extracted requested anonymous information from the medical charts of 153 qualified patients. Qualified patients had received a starting dose of 200 mg/day niraparib for recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and were in complete or partial response to platinum-based chemotherapy.
Results: Of the 153 patients, 56 (37%) experienced at least one of the three AEs evaluated within the first three months after niraparib initiation, and 49 (32%) experienced only grades 1/2 AEs. Among the 153 patients, fatigue was reported for 24% (36/153) (CI 17.4% - 31.0%); nausea for 16% (25/153) (CI 10.5% - 22.2%) and thrombocytopenia for 14% (21/153) (CI 8.3% - 19.2%). Of the 21 patients with thrombocytopenia, 3 were grade 3/4 severity (2% of overall). Among the patients, 4% (6/153) had a dose interruption, 11% reduced their dose (17/153), and 2% discontinued niraparib altogether (3/153) due to AEs.

Conclusions: While over 60% of patients in the phase 3 clinical trial reported experiencing the three AEs observed in the study, only 37% reported such in real-world usage. This difference may be due to the higher dosing in the trial study (initial dose of 300 mg/day vs. 200 in the observational study). Additional real-world research is needed to understand the effects of niraparib dosing on AEs.

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