Rubraca

(rucaparib)

New Product Slideshow

MPR

Introduction

- **Brand name:** Rubraca
- **Generic name:** Rucaparib
- **Pharmacological class:** Poly (ADP-ribose) polymerase (PARP) inhibitor
- **Strength and Formulation:** 200mg, 300mg; tablets
- **Manufacturer:** Clovis Oncology
- **How supplied:** Bottle—60
- **Legal Classification:** Rx

Rubraca


NDC 69660-203-91
Rubraca™
(rucaparib) tablets
300 mg*
60 tablets
Rx only
Keep out of reach of children

Indications

- Monotherapy in patients with deleterious BRCA-mutation (germline and/or somatic) associated advanced **ovarian cancer** who have been treated with ≥2 prior lines of chemotherapy
- Select patients for therapy based on an FDA-approved companion diagnostic test

Dosage & Administration

- Swallow whole
- 600mg twice daily until disease progression or unacceptable toxicity
- Dose modifications or adjustments for adverse reactions:
  - 1st reduction: 500mg twice daily
  - 2nd reduction: 400mg twice daily
  - 3rd reduction: 300mg twice daily

Considerations for Special Populations

- **Pregnancy:** Avoid
- **Nursing mothers:** Not recommended (during and for 2 weeks after last dose)
- **Pediatric:** Not established
- **Elderly:** No overall differences in safety observed

Warnings/Precautions

- **Monitor** CBC at baseline and monthly thereafter; do not start therapy until recovery from hematological toxicity due to previous chemotherapy (Grade ≤1)

- **Discontinue** if myelodysplastic syndrome/acute myeloid leukemia (MDS/AML) is confirmed

Warnings/Precautions

- Embryo-fetal toxicity
- Females of reproductive potential must obtain **pregnancy test** prior to initiating therapy
- Use **effective contraception** during therapy and for at least 6 months after last dose

Adverse Reactions

- Nausea
- Fatigue
- Asthenia
- Vomiting
- Anemia
- Abdominal pain
- Dysgeusia
- Constipation
- Decreased appetite
- Diarrhea
- Thrombocytopenia
- Dyspnea
- Lab abnormalities

Mechanism of Action

- Rucaparib is an inhibitor of PARP enzymes, including PARP-1, PARP-2, and PARP-3, which play a role in DNA repair
- *In vitro* studies have shown that rucaparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, apoptosis, and cell death
- Increased rucaparib-induced cytotoxicity was observed in tumor cell lines with deficiencies in *BRCA1/2* and other DNA repair genes

Clinical Trials

- The efficacy of Rubraca was evaluated in 2 multicenter, single-arm, open-label clinical trials in 106 patients with advanced BRCA-mutant ovarian cancer who had progressed after at least 2 prior chemotherapies (Study 1 and Study 2)

Clinical Trials

- All patients had received at least 2 prior platinum-based chemotherapies and 43% had received at least 3 or more prior lines of chemotherapy
- The median age was 59 years (range: 33 to 84 years) and they all had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

Clinical Trials

- All of the study patients received Rubraca 600mg twice daily as monotherapy until disease progression or unacceptable toxicity

- **Objective response rate** (ORR) and **duration of response** (DOR) were assessed by the investigator and independent radiology review (IRR) according to the RECIST version 1.1

Clinical Trials

- The investigator-assessed ORR was 54% (95% CI: 44, 64)
- A **complete** response was seen in 9% of patients and a **partial** response was seen in 45% of patients
- The median DOR was 9.2 months (95% CI: 6.6, 11.6)
- The response assessment by IRR was 42% (95% CI: 32, 52) with a median DOR of 6.7 months (95% CI: 5.5, 11.1)

Clinical Trials

- Investigator-assessed ORR was 66% (95% CI: 54, 76) in platinum-sensitive patients, 25% (95% CI: 9, 49) in platinum-resistant patients, and 0% (95% CI: 0, 41) in platinum-refractory patients
- The ORR was similar for patients with a BRCA1 gene mutation or BRCA2 gene mutation
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/rubraca/drug/34641/