Rubraca®
(rucaparib) 300 mg tablets

THE SHIELD AGAINST PROGRESSION IN mCRPC

Enhance your ability to fight *BRCA*-mutated mCRPC at its core with RUBRACA[1]

RUBRACA is the ONLY PARPi that can be used as a monotherapy following ANY androgen receptor-directed therapy and a taxane-based chemotherapy[1-4]*

*Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

BRCA, BReast CAncer gene; mCRPC, metastatic castration-resistant prostate cancer; PARPi, poly (adenosine diphosphate-ribose) polymerase inhibitor.

INDICATION

RUBRACA® (rucaparib) is indicated for the treatment of adult patients with a deleterious *BRCA* mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please see Important Safety Information throughout and full Prescribing Information.

TARGETED CONTROL FOR EFFECTIVE OUTCOMES[5]

Results based on the TRITON2 study*

46%

OBJECTIVE RESPONSE RATE (ORR)†
(n=37/81; 95% CI, 35%-57%)

15.5 MONTHS

MEDIAN DURATION OF RESPONSE (DOR)
(95% CI, 6.4-NOT REACHED)

67%

OF IRR-EVALUABLE PATIENTS HAD A ≥30% REDUCTION IN TARGET LESION SIZE FROM BASELINE

RUBRACA PROVIDES A TARGETED APPROACH AND SHOWS CLINICALLY MEANINGFUL‡ OUTCOMES IN PATIENTS WITH *BRCA*-MUTATED mCRPC

***Study design:** TRITON2 was a multicenter, single-arm, phase 2 clinical trial in patients with germline or somatic *BRCA*-mutated mCRPC previously treated with any androgen receptor-directed therapy and a taxane-based chemotherapy. Efficacy results were based on the independent radiology review (IRR)–evaluable population (N=81). The primary endpoint was ORR, and DOR was a secondary endpoint.

† ORR was defined per modified RECIST (Response Evaluation Criteria in Solid Tumours) v1.1 criteria and with no confirmed bone progression per Prostate Cancer Working Group 3 (PCWG3).

‡ Demonstrated improvements in multiple efficacy outcomes: confirmed ORR by IRR, 46% (95% CI, 35%-57%); median DOR by IRR, 15.5 months (95% CI, 6.4-not reached).

SELECT IMPORTANT SAFETY INFORMATION

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML) occur in patients treated with RUBRACA, and are potentially fatal adverse reactions. In 1594 treated patients with ovarian cancer, MDS/AML occurred in 32 patients (2%), including those in long term follow-up. Of these, 14 occurred during treatment or during the 28-day safety follow-up (0.9%). The duration of RUBRACA treatment prior to the diagnosis of MDS/AML ranged from < 2 months to approximately 72 months. The cases were typical of secondary MDS/cancer therapy-related AML; in all cases, patients had received previous platinum-containing chemotherapy regimens and/or other DNA damaging agents.

In ARIEL3, of patients with a germline and/or somatic *BRCA* mutation treated with RUBRACA, MDS/AML occurred in 9 out of 129 (7%) patients treated with RUBRACA and 4 out of 66 (6%) patients treated with placebo. The duration of therapy with RUBRACA in patients who developed secondary MDS/cancer therapy-related AML varied from 1.2 to 4.7 years.

In TRITON2, MDS/AML was not observed in patients with mCRPC (n=209) regardless of homologous recombination deficiency (HRD) mutation.

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MANAGEABLE SAFETY AND TOLERABILITY PROFILE[1]

Adverse Reactions (ARs) Reported in ≥20% of Patients With *BRCA*-Mutated mCRPC in TRITON2

Adverse reaction	RUBRACA (N=115)	
	Grades 1-4 (%)*	Grades 3-4 (%)
General disorders and administration site conditions		
Asthenia/fatigue	62	9
Gastrointestinal disorders		
Nausea	52	3
Constipation	27	1
Vomiting	22	1
Diarrhea	20	0
Blood and lymphatic system disorders		
Anemia	43	25
Thrombocytopenia†	25	10
Metabolism and nutrition disorders		
Decreased appetite	28	2
Skin and subcutaneous tissue disorders		
Rash‡	27	2
Investigations		
ALT/AST increased	33	5

Fatal ARs occurred in 2 patients (1.7%), 1 each attributed to acute respiratory distress syndrome and pneumonia

*National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03.

† Includes platelet count decreased.

‡ Includes blister, blood blister, dermatitis, dermatitis contact, eczema, genital rash, palmar-plantar erythrodysesthesia syndrome, photosensitivity reaction, psoriasis, rash, rash maculo-papular, rash pruritic, skin exfoliation, skin lesion, urticaria.

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ALT, alanine aminotransferase; AST, aspartate aminotransferase.

SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

Do not start RUBRACA until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ Grade 1). Monitor complete blood counts for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities (> 4 weeks), interrupt RUBRACA or reduce dose and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks or if MDS/AML is suspected, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue RUBRACA.

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SEE WHY RUBRACA IS THE PARPi YOU NEED TO FIGHT mCRPC.
VISIT RubracaProstateHCP.com

SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

Based on findings from genetic toxicity and animal reproduction studies, RUBRACA can cause fetal harm. Advise male patients with female partners of reproductive potential or who are pregnant to use effective methods of contraception during treatment and for 3 months following last dose of RUBRACA. Advise male patients not to donate sperm during therapy and for 3 months following the last dose of RUBRACA.

Most common adverse reactions of patients with *BRCA*-mutated mCRPC in TRITON2 (≥ 20%; Grade 1-4) were fatigue/asthenia (62%), nausea (52%), anemia (43%), AST/ALT elevation (33%), decreased appetite (28%), rash (27%), constipation (27%), thrombocytopenia (25%), vomiting (22%), and diarrhea (20%).

Concomitant administration of RUBRACA with CYP1A2, CYP3A, CYP2C9, or CYP2C19 substrates can increase the systemic exposure of these substrates, which may increase the frequency or severity of adverse reactions of these substrates. If concomitant administration is unavoidable between RUBRACA and substrates of these enzymes where minimal concentration changes may lead to serious adverse reactions, decrease the substrate dosage in accordance with the approved prescribing information.

If concomitant administration with warfarin (a CYP2C9 substrate) cannot be avoided, consider increasing the frequency of international normalized ratio (INR) monitoring.

For medical information inquiries within the U.S., contact pharma& at medinfo.us@pharmaand.com.

You may report adverse events to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Alternatively, to report an adverse event or reaction, contact pharma& by calling 1-800-506-8501 or emailing pv@pharmaand.com.

To report a product complaint, contact pharma& at complaints@pharmaand.com.

Please see full Prescribing Information.

References: 1. RUBRACA (rucaparib). Prescribing Information. pharma& Schweiz GmbH. 2023. **2.** Lynparza (olaparib). Prescribing Information. AstraZeneca Pharmaceuticals LP. 2023. **3.** Akeega (niraparib and abiraterone acetate). Prescribing Information. Janssen Biotech, Inc. 2023. **4.** Talzenna (talazoparib). Prescribing Information. Pfizer Inc. 2024. **5.** Abida W, Campbell D, Patnaik A, et al. Rucaparib for the treatment of metastatic castration-resistant prostate cancer associated with a DNA damage repair gene alteration: final results from the phase 2 TRITON2 study. *Eur Urol*. 2023;84(3):321-330.

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The individuals pictured in this piece are models, and the images are being used for illustrative purposes only.