

Rubraca[®]
(rucaparib) 300 mg
tablets



THE SHIELD AGAINST PROGRESSION IN mCRPC

Challenge the PARPi Treatment Paradigm

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. 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.

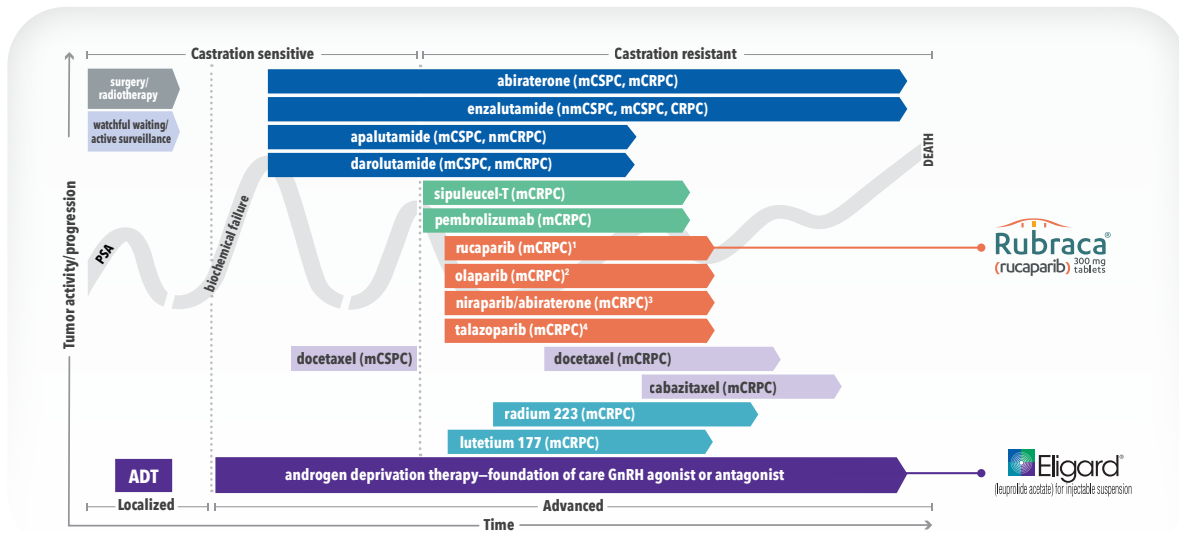
This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please see Important Safety Information throughout and full [Prescribing Information](#).

THE RUBRACA DIFFERENCE

mCRPC TREATMENT CAN BE COMPLEX AND INVOLVE A WIDE VARIETY OF THERAPIES⁵⁻⁷

Consider factors such as stage and type of prostate cancer, treatment history, and genetic tests to guide therapeutic approach



- Treatment can involve a wide variety of therapies, including surgery, radiation therapy, androgen receptor-directed therapies, chemotherapy, immunotherapy, and targeted treatments such as PARP inhibitors
- ADTs like ELIGARD are a foundation of treatment for advanced prostate cancer⁸
- PARPis like RUBRACA are beneficial for patients with hereditary risk factors that predispose them to impaired DNA repair, such as certain *BRCA* mutations⁹

GENETIC TESTING FOR *BRCA* MUTATIONS IS IMPORTANT TO CONFIRM PARPis ARE AN APPROPRIATE TREATMENT OPTION FOR PATIENTS WITH mCRPC^{1-4,10}

ELIGARD® (leuprolide acetate) for injectable suspension is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of advanced prostate cancer.

ELIGARD may impair fertility in males of reproductive potential.

For Important Safety Information and full Prescribing Information for ELIGARD, visit EligardHCP.com.

ADT, androgen deprivation therapy; CRPC, castration-resistant prostate cancer; mCSPC, metastatic castration-sensitive prostate cancer; nmCRPC, nonmetastatic castration-resistant prostate cancer; nmCSPC, nonmetastatic castration-sensitive prostate cancer; PSA, prostate-specific antigen.

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/cancer therapy-related 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.

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CHALLENGE THE CURRENT PARPi STANDARD OF CARE WITH RUBRACA

There are 4 PARPis approved for mCRPC, all of which have different treatment requirements:¹⁻⁴

RUCAPARIB	OLAPARIB	TALAZOPARIB	NIRAPARIB
Can be used as a monotherapy for <i>BRCA</i> -mutated mCRPC following ANY androgen receptor-directed therapy and a taxane-based chemotherapy*	<ul style="list-style-type: none"> To be used as a monotherapy following enzalutamide or abiraterone in HRR-mutated mCRPC To be used in combination with abiraterone and either prednisone or prednisolone in <i>BRCA</i>-mutated mCRPC 	To be used in combination with enzalutamide in HRR-mutated mCRPC	To be used as a fixed combination with abiraterone in <i>BRCA</i> -mutated mCRPC, taken in combination with prednisone

Direct clinical comparisons between PARPis cannot be made in the absence of a head-to-head trial.

PROVIDE A FLEXIBLE, TARGETED, EFFECTIVE, AND SUPPORTIVE TREATMENT



FLEXIBLE

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*}



TARGETED

Specifically treats **BRCA-mutated mCRPC** patients.¹



EFFECTIVE

Demonstrated **clinically meaningful**[†] results.¹¹



SUPPORTIVE

Offers **comprehensive support** for your patients and access support for your practice.

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 GnRH analog concurrently or should have had bilateral orchiectomy.

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

DOR, duration of response; IRR, independent radiology review; ORR, objective response rate.

SELECT IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

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

SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

Do not start RUBRACA until patients have recovered from hematological toxicity caused by previous chemotherapy (\leq 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.

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 ($\geq 20\%$; 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](mailto:pharma&@medinfo.us).

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&](mailto:pharma&@pharmaand.com) by calling 1-800-506-8501 or emailing pv@pharmaand.com.

To report a product complaint, contact [pharma& at complaints@pharmaand.com](mailto:pharma&@complaints.pharmaand.com).

Please see full Prescribing Information.

References: 1. RUBRACA (rucaparib). Prescribing Information. [pharma& Schweiz GmbH](https://www.pharmaand.com). 2023. 2. Lynparza (olaparib). Prescribing Information. AstraZeneca Pharmaceuticals LP. 2023. 3. Akeega (talazoparib). Prescribing Information. Janssen Biotech, Inc. 2023. 4. Talzenna (talazoparib). Prescribing Information. Pfizer Inc. 2024. 5. Rebello RJ, Oing C, Knudsen KE, et al. Prostate cancer. *Nat Rev Dis Primers*. 2021;7(1):9. 6. Gillette CM, Yette GA, Cramer SD, Graham LS. Management of advanced prostate cancer in the precision oncology era. *Cancers (Basel)*. 2023;15(9):2552. 7. Wahner A. Onclive. December 1, 2023. <https://www.onclive.com/view/novel-combination-regimens-are-expanding-the-prostate-cancer-treatment-paradigm> 8. ELIGARD (leuprolide acetate). Prescribing Information. Tolmar, Inc. 2024. 9. Tisseverashinghe S, Bahoric B, Anidjar M, Probst S, Niazi T. Advances in PARP inhibitors for prostate cancer. *Cancers (Basel)*. 2023;15(6):1849. 10. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Prostate Cancer V.4.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 20, 2024. To view the most recent and complete version of the guideline, go online to [NCCN.org](https://www.nccn.org). NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. 11. 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;84:321-330.