

**Rubraca**<sup>®</sup>  
(rucaparib) 300 mg  
tablets



# THE SHIELD AGAINST PROGRESSION IN mCRPC

Help your patients fight **BRCA**-mutated mCRPC with **RUBRACA**

RUBRACA is the **ONLY** PARPi that can be used as a monotherapy following **ANY** androgen receptor-directed therapy and a taxane-based chemotherapy<sup>1-4\*</sup>

\*Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. *BRCA*, *BR*east *C*Ancer gene; mCRPC, metastatic castration-resistant prostate cancer; PARPi, poly (adenosine diphosphate-ribose) polymerase inhibitor.

## INDICATION

RUBRACA<sup>®</sup> (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.

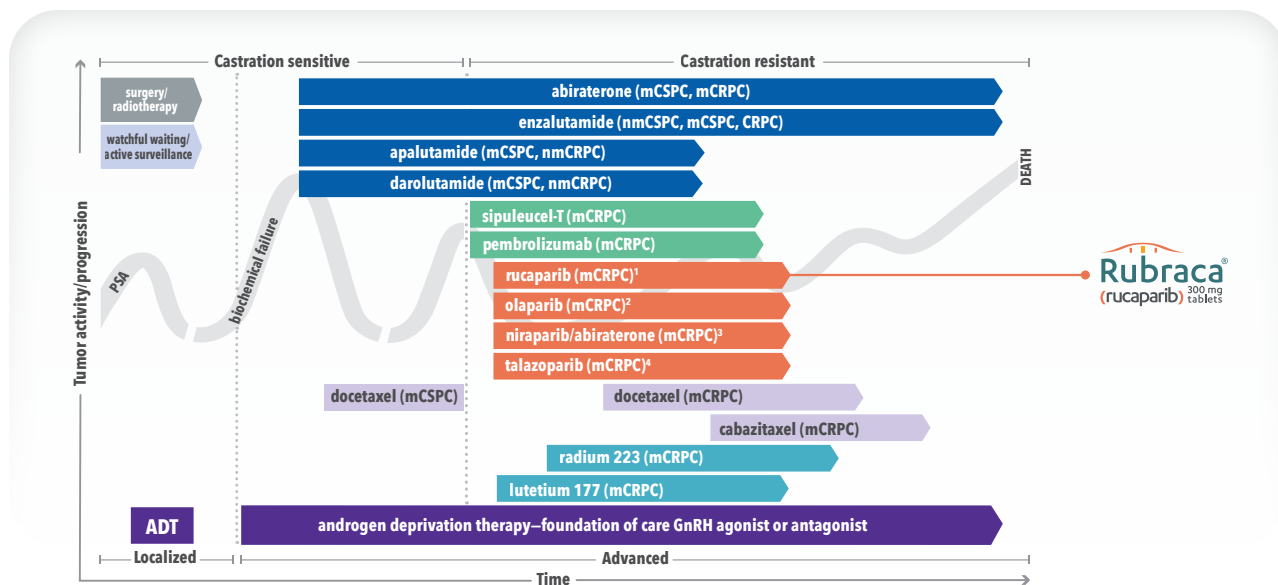
This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please see Important Safety Information throughout and full Prescribing Information.

**THE RUBRACA DIFFERENCE**

# YOU PLAY A CRUCIAL ROLE IN THE CARE OF PATIENTS WITH mCRPC

mCRPC treatment is complex and may involve a wide variety of care considerations<sup>5-7</sup>



Source: Fig et al. Springer; 2010.

Part of caring for patients with mCRPC is helping them better understand what to expect from treatment

Points of discussion may include disease and treatment history, genetic testing, treatment sequencing, available resources, and financial implications of treatment. When determining treatment, consider:

- Efficacy and safety profiles
- How dosing and administration may influence adherence
- Concomitant treatment and potential interactions
- Supportive care options for tolerability concerns

**WHILE ALL PARPis SHARE A SIMILAR MECHANISM OF ACTION, THEIR CLINICAL PROFILES VARY. KNOWING THEIR DIFFERENCES CAN HELP IN MAKING TREATMENT DECISIONS FOR PATIENTS<sup>1-4</sup>**

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/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.

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



# RUBRACA CHALLENGES THE CURRENT PARPi STANDARD OF CARE FOR PATIENTS WITH BRCA-MUTATED mCRPC

<b>FLEXIBLE</b>	RUBRACA is the <b>ONLY</b> PARPi that can be used as a monotherapy following <b>ANY</b> androgen receptor-directed therapy and a taxane-based chemotherapy <sup>1-4*</sup>
<b>TARGETED</b>	Specifically treats <b>BRCA-mutated mCRPC</b> patients <sup>1</sup>
<b>EFFECTIVE</b>	Demonstrated <b>clinically meaningful<sup>†</sup></b> results <sup>8</sup>
<b>SUPPORTIVE</b>	Offers <b>comprehensive support</b> for your patients and access support for your practice

\*Patients should also receive a GnRH analog concurrently or should have had bilateral orchiectomy.

<sup>†</sup>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).

## Targeted control for effective outcomes<sup>1,8</sup>

### Results based on the TRITON2 study<sup>8†</sup>

46%

**OBJECTIVE  
RESPONSE RATE<sup>§</sup>**  
(n=37/81; 95% CI, 35%-57%)

15.5  
MONTHS

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

67%

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

**\*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 IRR-evaluable population (N=81). The primary endpoint was ORR, and DOR was a secondary endpoint.

<sup>§</sup>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).

### Patient eligibility should first be determined through germline or tumor genetic testing for mutations such as BRCA alterations<sup>1-4,9</sup>

Ensure patients speak with their healthcare professional or genetic counselor to understand test results and how they relate to the use of PARPis.

**EDUCATING PATIENTS ABOUT RUBRACA CAN HELP INFORM TREATMENT DECISIONS AND SET EXPECTATIONS**

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

### SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

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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# HELP YOUR PATIENTS TAKE CONTROL OF mCRPC WITH TWICE-DAILY ORAL DOSING<sup>1</sup>



**The recommended dose of RUBRACA is 600 mg (two 300-mg tablets) taken orally twice daily with or without food, for a total daily dose of 1,200 mg**

- Continue treatment with RUBRACA until disease progression or unacceptable toxicity
- Patients receiving RUBRACA for mCRPC should also receive a GnRH analog concurrently or should have had bilateral orchiectomy
- To manage adverse reactions (ARs), consider interrupting treatment or reducing dose

## Dosing Modifications Recommended to Help Manage ARs

Dose reduction	Dose
Starting dose	600 mg twice daily (two 300-mg tablets)
First dose reduction	500 mg twice daily (two 250-mg tablets)
Second dose reduction	400 mg twice daily (two 200-mg tablets)
Third dose reduction	300 mg twice daily (one 300-mg tablet)

## Dose interruptions due to an AR occurred in 57% of patients receiving RUBRACA

- ARs requiring dose interruption in >3% of patients included anemia, thrombocytopenia, asthenia/fatigue, nausea, vomiting, neutropenia, ALT/AST increased, creatinine increased, decreased appetite, acute kidney injury, and hypophosphatemia

## Dose reductions due to an AR occurred in 41% of patients receiving RUBRACA

- ARs requiring dose reductions in >3% of patients were anemia (14%), asthenia/fatigue (10%), thrombocytopenia (7%), nausea (6%), decreased appetite (4%), and rash (3%)

## Missed dose

- If a patient misses a dose of RUBRACA, instruct the patient to take the next dose at the next scheduled time. Vomited doses should not be replaced

## Drug-drug interactions

- RUBRACA may interact with certain CYP1A2, CYP3A, CYP2C9, or CYP2C19 substrates
- Ensure each patient's medications are fully documented and carefully reviewed by their clinical care team. Please refer to the full Prescribing Information for more details about specific interactions
- Dosage modifications may be considered to minimize drug-drug interactions

ALT, alanine aminotransferase; AST, aspartate transaminase.

## 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.

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







## HELPING PATIENTS UNDERSTAND HOW TO MANAGE POTENTIAL SAFETY AND TOLERABILITY CONCERNS

RUBRACA offers manageable safety and tolerability<sup>1</sup>

### ARs reported in $\geq 20\%$ of patients with *BRCA*-mutated mCRPC in TRITON2

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

Regular monitoring is recommended to prevent and/or reduce the likelihood and impact of side effects<sup>1</sup>

### For gastrointestinal side effects, consider<sup>1,10</sup>:

- Over-the-counter medications and lifestyle changes
- Dose interruption, reduction, or both if toxicity of grade 2 and above remains

### When encountering hematological side effects<sup>1</sup>:

- Perform blood counts prior to starting treatment and every month during treatment
- Consider dose interruption or reduction for prolonged toxicity ( $>4$  weeks) and monitor blood counts weekly until recovery
- Refer to a hematologist if levels have not recovered to grade 1 or less after 4 weeks or if MDS/AML is suspected
- Discontinue RUBRACA if MDS/AML is confirmed

AML, acute myeloid leukemia; MDS, myelodysplastic syndromes.

### 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.

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# OFFERING COMPREHENSIVE SUPPORT TO HELP ENSURE ACCESS

Programs offered for RUBRACA can help patients and healthcare professionals navigate treatment



## QUICKSTART PROGRAM\*

- Helps patients start RUBRACA if they experience coverage delays regardless of income or insurance. Eligible patients receive a 15-day supply of RUBRACA for up to 60 days (2 months) while coverage is pending or until alternate funding resources have been identified and approved



## COVERAGE LINK PROGRAM\*

- Provides a free supply of RUBRACA in 15-day increments (up to 90 days) for eligible patients who experience a change in commercial insurance status, which includes changing to a new insurer following a job change or switching plans during an employer's annual enrollment period



## RUBRACA CO-PAY ASSISTANCE PROGRAM\*\*

- As little as \$0 co-pay program for eligible patients with private or commercial insurance who are prescribed RUBRACA



## PATIENT ASSISTANCE PROGRAM (PAP)\*

- Available for eligible patients who are uninsured or cannot afford medication

\*Terms & Conditions may apply.

### †TERMS & CONDITIONS FOR THE pharma& CO-PAY PROGRAM

- This offer is only available to patients with commercial insurance. The program is not available for patients who receive reimbursement under any federal, state or government-funded insurance programs, including patients who: (i) are enrolled in Medicare, Medicare Advantage, Medigap, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program; (ii) are not using insurance coverage at all; (iii) are enrolled in an insurance plan that reimburses for the entire cost of the drug; or (iv) where product is not covered by patient's insurance
- The value of this program is exclusively for the benefit of patients and is intended to be credited toward patient out-of-pocket obligations, including applicable co-payments, coinsurance, and deductibles. You agree that you are personally responsible for paying any amount of co-pay required after the savings card is applied
- May not be available if your insurance company or health plan implements either an accumulator adjustment or co-pay maximizer program. Patient is responsible for complying with any applicable limitations and requirements of his/her health plan related to the use of the program. The program may not be used if prohibited by a patient's health insurer
- Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. This program may not be combined with any other financial assistance program, free trial, discount, rebate, coupon, or other offer
- Program is not valid where prohibited by law. Valid only in the United States and Puerto Rico. This program is not health insurance
- pharma& reserves the right to make eligibility determinations and to rescind, revoke, or amend the program and discontinue support at any time without notice
- For complete information about the Terms & Conditions of this program, including the limitations on use and the amount of assistance, go to [www.RubracaProstateHCP.com](http://www.RubracaProstateHCP.com) or call 1-844-779-7707

These Terms & Conditions are effective as of 01/01/2025.

Please see full Terms & Conditions for the Co-Pay Program and all other access programs at [www.RubracaProstateHCP.com/access-and-support](http://www.RubracaProstateHCP.com/access-and-support).

TO LEARN MORE AND ACCESS THESE RESOURCES, VISIT [RubracaProstateHCP.com](http://RubracaProstateHCP.com)

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# PROVIDE PERSONALIZED SUPPORT FOR PATIENTS WITH ADVANCED PROSTATE CANCER

## INCRE/MENTAL

IncreMENTal is the only habit-building program to support patients and their caregivers as they build a healthier lifestyle

**IncreMENTal gives patients small, simple actions that add up over time to help overcome their treatment challenges. Fully online courses have:**



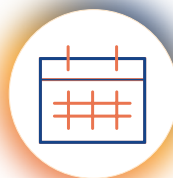
**Easy-to-follow food, fitness, and mental health tips**



**Personal progress tracking to help set and keep goals**



**Comprehensive information in a simple, digestible format**



**New weekly information to help change habits step by step**

Lessons are completed at the pace of the user, and patients are able to download and print lessons to keep with them as they control their own progress.

**Learn more at [IncreMENTalADT.com](https://www.IncreMENTalADT.com)**

Please see 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](https://www.RubracaProstateHCP.com)

#### SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

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:medinfo.us@pharmaand.com).

You may report adverse events to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://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](mailto:pv@pharmaand.com).

To report a product complaint, contact pharma& at [complaints@pharmaand.com](mailto: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.** 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.** Waher A. OnLive. December 1, 2023. <https://www.onlive.com/view/novel-combination-regimens-are-expanding-the-prostate-cancer-treatment-paradigm> **8.** 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. **9.** 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](http://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. **10.** LaFargue CJ, Dal Molin GZ, Sood AK, Coleman RL. Exploring and comparing adverse events between PARP inhibitors. *Lancet Oncol*. 2019;20(1):e15-e28.

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