# Prescribing Information
## Rubraca® (rucaparib) film-coated tablets

Consult Summary of Product Characteristics (SmPC) before prescribing.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

### Indication:

Rubraca is indicated as monotherapy for the maintenance treatment of adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Rubraca is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

### Presentation and active ingredients:

**Rubraca 200 mg film-coated tablets** each tablet contains rucaparib camsylate corresponding to 200 mg rucaparib.
**Rubraca 250 mg film-coated tablets** each tablet contains rucaparib camsylate corresponding to 250 mg rucaparib.
**Rubraca 300 mg film-coated tablets** each tablet contains rucaparib camsylate corresponding to 300 mg rucaparib.

### Excipients:

This medicine contains less than 1 mmol sodium (23 mg) per tablet, essentially 'sodium-free'.

### Dosage and administration:

The recommended dose of Rubraca is 600 mg (two 300 mg tablets) twice daily, equivalent to a total daily dose of 1200 mg, until disease progression or unacceptable toxicity. Rubraca tablets can be taken with or without food, and approximately 12 hours apart. If a dose is missed or if the patient experiences vomiting, they should resume taking Rubraca with the next scheduled dose.

**Dosage adjustments**: Moderate to severe adverse reactions (i.e. CTCAE Grade 3 or 4) may be managed through dose interruptions and/or dose reductions. Liver transaminase elevations (aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) occur early in treatment and are generally transient. Grade 1 to 3 elevations in AST/ALT can be managed without change to the Rubraca dose, or with treatment modification (interruption and/or dose reduction). All Grade 4 reactions require treatment modification. Other moderate to severe non-haematological adverse reactions such as nausea and vomiting, can be managed through dose interruption and/or reductions, if not adequately controlled by appropriate symptomatic management. **Elderly**: No adjustment in starting dose is required. There are limited clinical data in patients aged 75 or over. **Renal impairment**: No adjustment in starting dose is required in patients with mild or moderate renal impairment. There are no clinical data in patients with severe renal impairment (CLcr less than 30mL/min). Therefore, Rubraca is not recommended in patients with severe renal impairment. Rubraca may only be used in patients with severe renal impairment if the benefit outweighs the risk. Patients with moderate or severe renal impairment should be carefully monitored for renal function and adverse reactions. **Hepatic impairment:** No starting dose adjustment is required in patients with mild or moderate hepatic impairment. Patients with moderate hepatic impairment should be carefully monitored for hepatic function and adverse reactions. There are no clinical data in patients with severe hepatic impairment (i.e. total bilirubin > 3 times ULN), therefore Rubraca is not recommended for use in patients with severe hepatic impairment. Consult SmPC for dose adjustment recommendations.

### Duration of treatment:

First-line maintenance treatment of advanced ovarian cancer: Patients can continue treatment until disease progression, unacceptable toxicity or completion of 2 years treatment.

Maintenance treatment of platinum-sensitive relapsed ovarian cancer: Patients can continue treatment until disease progression or unacceptable toxicity.

### Contraindications:

Hypersensitivity to the active substance or to any of the excipients. Breast- feeding during treatment and for 2 weeks after final dose.

### Warnings and precautions:

**Haematological toxicity**: Patients should not start Rubraca until they have recovered from haematological toxicities caused by previous chemotherapy (≤ CTCAE Grade 1). Complete blood count testing prior to starting treatment with Rubraca and monthly thereafter is advised. Rubraca should be interrupted or dose reduced, and blood counts monitored weekly until recovery for the management of low blood counts. **Myelodysplastic syndrome/acute myeloid leukemia (MDS/AML):** If MDS/AML is suspected, the patient should be referred to a haematologist for further Investigation. If MDS /AML is confirmed, Rubraca should be discontinued. **Photosensitivity**: Patients should avoid spending time in direct sunlight as they may burn more easily. When outdoors, patients should wear protective clothing and sunscreen and lip balm with SPF of 50 or greater.

**Gastrointestinal toxicities**: Low grade (CTCAE Grade 1 or 2) nausea and vomiting may be managed with dose reduction or interruption. Additionally, antiemetics may be considered for treatment or prophylaxis.

### Drug interactions:

**Effect of other medicinal products on Rubraca**: Enzymes responsible for Rubraca metabolism have not been Identified. Although *in vitro* Rubraca metabolism mediated by CYP3A4 was slow, a significant contribution of CYP3A4 *in vivo* cannot be excluded. Caution should be used for concomitant use of strong CYP3A4 inhibitors or inducers. *In vitro*, Rubraca was shown to be a substrate of P-gp and BCRP. Effect of P-gp, and BCRP inhibitors on Rubraca PK cannot be ruled out. Caution is recommended when Rubraca is co-administered with medicinal products that are strong inhibitors of P-gp. **Effects of Rubraca on other medicinal products**: When co-administering medicinal products metabolised by CYP1A2, particularly medicines which have a narrow therapeutic Index (e.g., tizanidine, theophylline), dose adjustments may be considered based on appropriate clinical monitoring. When co-administering medicinal products that are CYP2C9 substrates with a narrow therapeutic index (e.g., warfarin, phenytoin), dose adjustments may be considered, if clinically indicated. Caution should be exercised and additional International Normalised Ratio (INR) monitoring with co-administration of warfarin and therapeutic drug level monitoring of phenytoin should be considered, if used concomitantly with Rubraca. Caution is advised when co-administering medicinal products that are CYP3A substrates with a narrow therapeutic index (e.g., alfentanil, astemizole, cisapride, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus, terfenadine). Dose adjustments may be considered, if clinically indicated based on observed adverse reactions. No dose adjustment is recommended for co-administered oral contraceptives. No dose adjustment is recommended for co-administered medicinal products that are CYP2C19, P-gp. or BCRP substrates. Rubraca is a potent inhibitor of MATE1 and MATE2·K, a moderate Inhibitor of OCT1, and a weak inhibitor of OCT2. As inhibition of these transporters could decrease metformin renal elimination and decrease liver uptake of metformin, caution Is advised when metformin is co-administered with Rubraca. The clinical relevance of UGT1A1 inhibition by Rubraca is not clear. Caution should be used when Rubraca is co-administered with UGT1A1 substrates (i.e. irinotecan) to patients with UGT1A1*28 (poor metaboliser) due to a possible increase in the exposure of SN-38 (the active metabolite of irinotecan) and associated toxicities.

### Fertility, pregnancy and lactation:

Women of childbearing potential should be advised to avoid becoming pregnant while on Rubraca, and for six months following the last dose of Rubraca. A pregnancy test before initiating treatment is recommended in women of reproductive potential. Rubraca may cause foetal harm when administered to a pregnant woman. No studies have been conducted with Rubraca in breastfeeding women. Rubraca must not be used during breast-feeding.

### Ability to drive and use machines:

Caution when driving or using machines is advised for patients that report fatigue, nausea, or dizziness during treatment with Rubraca.

### Undesirable events:

Very common: anaemia, thrombocytopenla, neutropenia, decreased appetite, increased blood creatinine, dysgeusia, dizziness, dyspnoea, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, increased alanine aminotransferase, increased aspartate aminotransferase. photosensitivity reaction, fatigue, pyrexia. Common; Myelodysplastic syndrome/Acute myeloid leukemia, hypersensitivity, leukopenia, lymphopenia, febrile neutropenia, hypercholesterolemia, dehydration, increased transaminases, rash, rash maculo-papular, palmar-plantar erythrodysaesthesia syndrome, erythema. Prescribers should consult the SmPC in relation to other adverse reactions.

### Marketing authorisation number:

For Great Britain: PLGB 54599/0011, PLGB 54599/0012, PLGB 54599/0013

For Northern Ireland: EU/1/17/1250/001, EU/1/17/1250/002, EU/1/17/1250/003

### Marketing authorisation holder:

pharmaand GmbH, Taborstrasse 1, 1020 Vienna, Austria

### List price:

£3,562.00GBP per pack of 60 film coated tablets (200mg,250mg,300mg)

### Legal classification:

POM (Prescription Only Medicine)

### Date of creation/revision of the text:

**May 2024**

**Summary of Product Characteristics.** Updated May 2024, pharmaand GmbH., available at **MHRA products** (Accessed: July 2025).

Adverse events should be reported. Reporting forms and information can be found at https:/yellowcard.mhra.gov.uk/ or via the MHRA Yellow Card app, available in the Google Play or Apple App Stores. Adverse events should also be reported to pharmaand GmbH (pharma&) on pv@pharmaand.com

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