Rucaparib (Tablets) Monotherapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
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.	C56 C48 C57	00904a 00904b 00904c	N/A

* This applies to post 2012 indications

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patients individual clinical circumstances.

Rucaparib is taken twice daily continuously for a maximum of two years or until disease progression or unacceptable toxicity develops, whichever is first.
Patients should start the maintenance treatment with rucaparib no later than 8 weeks after completion of their final dose of the platinum containing regimen.

Drug	Dose	Route	Cycle
Rucaparib	600mg twice daily	PO[a,b,c,d]	Continuous
[a] Rucaparib tablets can be taken with or without food. The doses should be taken approximately 12 hours apart.			
[b] Rucaparib tablets should be swallowed whole with a large glass of water. The tablets should not be crushed or dissolved.			
[c] If a patient vomits after taking rucaparib, the patient should not retake the dose and should take the next scheduled dose.			
[d] If a dose is missed, the patient should resume taking rucaparib with the next scheduled dose.			

ELIGIBILITY:

- Indications as above
- ECOG 0-1
- Adequate haematological and organ function

CAUTIONS:

- Rucaparib may only be used in patients with severe renal impairment if the potential benefit outweighs the risk. Patients with moderate or severe renal impairment should be carefully monitored for renal function and adverse reactions. Discuss with consultant.
- Women of child-bearing potential unless on effective methods of regular contraception.

EXCLUSIONS:

- Hypersensitivity to rucaparib or any of the excipients
- Breastfeeding during treatment and for 2 weeks after the final dose

PRESCRIPTIVE AUTHORITY:

- The treatment plan must be initiated by a Consultant Medical Oncologist

TESTS:

Baseline tests:

- FBC, renal and liver profile
- Pregnancy test

Regular tests:

- Monthly FBC, renal and liver profile

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant.
- Adverse reactions may be managed through dose interruptions and/or dose reductions (see Table 1)

Table 1: Dose reduction of rucaparib for adverse events

Dose level	Dose reduction recommendation
Starting dose	600 mg twice daily (two 300 mg tablets twice daily)
Dose -1	500 mg twice daily (two 250 mg tablets twice daily)
Dose -2	400 mg twice daily (two 200 mg tablets twice daily)
Dose -3	300 mg twice daily (one 300 mg tablet twice daily)

Haematological:

Table 2: Dose modification of rucaparib in haematological toxicity*

ANC ($x10^9$/L)		Haemoglobin (g/dL)	Platelets ($X10^9$/L)	Dose
<1.0	Or	<8	<100	Interrupt treatment and monitor blood counts weekly until recovery to ≤Grade 1 (ANC ≥1.5 $x10^9$/L, haemoglobin ≥9.0g/dL and platelets ≥100 $X10^9$/L) On recovery, continue treatment with one dose level reduction. If blood counts do not recover to ≤Grade 1 after 4 weeks, discontinue treatment and refer to consultant for further investigation.
Confirmed diagnosis of myelodysplastic syndrome (MDS) or acute myeloid leukaemia (AML).				Permanently discontinue rucaparib

Renal and Hepatic Impairment:

Table 3: Recommended dose modification in renal and hepatic impairment

Renal Impairment		Hepatic Impairment	
CrCl (mL/minute)	**Dose**	**Level**	**Dose**
≥ 30 mL/minute	No dose adjustment is needed	Mild and moderate	No dose adjustment is needed
< 30 mL/minute	No need for dose adjustment is expected	Severe	Not recommended
Haemodialysis	No need for dose adjustment is expected		
Renal and hepatic dose modifications from Giraud et al 2023			

- Liver transaminase elevations (aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT)) occur early in treatment and are generally transient.

Table 4: Management of treatment-emergent AST/ ALT elevations

Grade of AST/ALT Elevation	Recommended dose modification
Grade 3 without other signs of liver dysfunction	Monitor LFTs weekly until resolution to Grade ≤ 2. Continue rucaparib, provided bilirubin is < ULN and alkaline phosphatase is < 3 × ULN. Interrupt treatment if AST/ALT levels do not decline within 2 weeks until Grade ≤ 2, then resume rucaparib at the same or at a reduced dose
Grade 4	Interrupt rucaparib until values return to Grade ≤ 2; then resume rucaparib with a dose reduction and monitor LFTs weekly for 3 weeks

Management of adverse events:

Table 5: Management of other non-haematological adverse reactions

Severity of reaction	Recommended dose modification
≥ Grade 3 non-haematological adverse reactions, e.g. nausea and vomiting	If not adequately controlled by appropriate symptomatic management, manage through dose interruption and/or reductions as clinically indicated (see Table 1)

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

- As outlined in NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting - Available on NCCP website

Rucaparib: Moderate to high* **(Refer to local policy)**

*Based on clinical experience, the emetogenic potential of rucaparib may be regarded as moderate as opposed to moderate to high.

For information:
Within NCIS regimens, antiemetics have been standardised by Medical Oncologists and Haemato-oncologists and information is available in the following documents:

- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Medical Oncology) - Available on NCCP website
- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Haemato-oncology) - Available on NCCP website

PREMEDICATIONS: None recommended

OTHER SUPPORTIVE CARE:

- Women of reproductive potential should be advised to use effective contraception during treatment and for 6 months following the last dose of rucaparib.
- Rucaparib has minor influence on the ability to drive and use machines. Caution when driving or using machines is advised for patients who report fatigue, nausea, or dizziness during treatment with rucaparib.
- GCSF support may be required **(Refer to local policy).**

ADVERSE EFFECTS:

- Please refer to the relevant Summary of Product Characteristics (SmPC) for details.

REGIMEN SPECIFIC COMPLICATIONS:

- **Myelodysplastic syndrome/acute myeloid leukaemia:** Myelodysplastic syndrome/acute myeloid leukaemia (MDS/AML), including cases with fatal outcome, have been reported in patients who received rucaparib. If MDS/AML is suspected, the patient should be referred to a haematologist for further investigations, including bone marrow analysis and blood sampling for cytogenetics. If, following investigation for prolonged haematological toxicity, MDS/AML is confirmed, rucaparib should be discontinued.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for information.

REFERENCES:

1. Monk BJ et al. A Randomized, Phase III Trial to Evaluate Rucaparib Monotherapy as Maintenance Treatment in Patients With Newly Diagnosed Ovarian Cancer (ATHENA-MONO/GOG-3020/ENGOT-ov45). J Clin Oncol. 2022 Dec 1;40(34):3952-3964. doi: 10.1200/JCO.22.01003. Epub 2022 Jun 6. PMID: 35658487; PMCID: PMC9746782.
2. Giraud E L, Lijster B D, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment: an update. Available at: https://pubmed.ncbi.nlm.nih.gov/37269847/
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Antiemesis Version 1.2025 – March 27, 2025. Accessed May 2025. Available at: https://www.nccn.org/login?ReturnURL=https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf
4. Rucaparib (Rubraca®) SmPC. Last updated: 03/04/2024. Accessed: May 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information_en.pdf

Version	Date	Amendment	Approved By
1	14/08/2025		Dr. Dearbhaile Collins

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.