Indication	As maintenance monotherapy treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who have a recent FIRST OR SUBSEQUENT relapse of platinum-sensitive disease who are now in response following a SECOND OR SUBSEQUENT platinum-based chemotherapy: a) who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation b) who do NOT have a deleterious or suspected deleterious germline and/or somatic BRCA mutation To start within 8 weeks of completing a minimum of 4 cycles of platinum-containing chemotherapy from the date of the last infusion. NB No previous treatment with a PARP inhibitor, unless an NHSE commissioned PARP inhibitor has had to be stopped within 3 months of starting, solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. A formal medical review as to whether maintenance treatment with rucaparib should continue or not will be scheduled to occur at least by the start of the third cycle of treatment.
Treatment Intent	Palliative.
Frequency and number of cycles	Repeat every 28 days. Continue until disease progression, unacceptable toxicity or patient's choice to stop treatment.
Monitoring Parameters pre-treatment	• FBC, U&E's and LFTs baseline and prior to each cycle. • Withhold if neutrophils < 1.0 and/or platelets < 75, and / or haemoglobin <80g/L, and monitor blood counts weekly until recovery, and consider dose reduction. • **Hepatic Impairment:** Not recommended for use in patients with moderate or severe hepatic impairment (Child-Pugh classification B or C, Bilirubin >1.5 x ULN). • **Renal Impairment:** No dose adjustment is required in patients with mild or moderate (CrCl 31-50 ml/min) renal impairment. No data available in severe impairment (CrCl <30ml/min), therefore rucaparib is not recommended for use, clinical decision to use. • **Drug Interactions:** Caution when rucaparib is co-administered with medicines that are strong inhibitors of P-gp (clarithromycin, erythromycin, ritonavir and verapamil), or strong CYP3A4 inhibitors (e.g., ketoconazole, ritonavir, clarithromycin, itraconazole, voriconazole, posaconazole) or inducers (e.g., carbamazepine, phenytoin, rifampin). Caution should be exercised and additional drug level monitoring / INR (as appropriate) when co-administered with medicinal products with a narrow therapeutic index metabolised by CYP1A2 (e.g. tizanidine, theophylline) and CYP2C9 (e.g warfarin, phenytoin). Caution 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). Caution is advised when metformin is co-administered with rucaparib.

	• **Dose Modification:** Moderate to severe (grade 3-4) haematological and non-haematological adverse reactions may require dose reduction. First dose reduction, 500 mg twice daily. Second dose reduction, 400 mg twice daily. Third dose reduction, 300 mg twice daily. • **Management of treatment emergent AST/ALT elevation:** Grade 3 (>5-20 x ULN) without other signs of liver dysfunction; Monitor LFTs weekly until resolution to ≤ 5 x ULN. Continue rucaparib provided bilirubin is < ULN and alkaline phosphatase is < 3 x ULN. Interrupt treatment if AST/ALT levels do not decline within 2 weeks until ≤ 5 x ULN, then resume rucaparib at the same or at a reduced dose. Grade 4 (>20 x ULN): Interrupt rucaparib until values return to ≤ 5 x ULN; then resume rucaparib with a dose reduction and monitor LFTs weekly for 3 weeks. • **AML/MDS:** Myelodysplastic syndrome/acute myeloid leukaemia (MDS/AML) has been reported in some patients receiving rucaparib. If haematological parameters have not recovered to CTCAE Grade 1 or better (ie neutrophils still < 1.5 and/or platelets still < 75) after 4 weeks, the patient should be referred to a haematologist for further investigations. If MDS/AML is confirmed treatment with rucaparib should be discontinued. • **Missed dose:** If a dose is missed, the patient should resume taking rucaparib with the next scheduled dose. If a patient vomits post dose they should not re take the dose and resume with the next scheduled dose. • Caution when driving or using machines is advised for patients who report fatigue, nausea, or dizziness during treatment. • **Photosensitivity:** Patients should be advised to avoid spending time in direct sunlight, and use appropriate protection with a hat, protective clothing and SPF 50 sunscreen when outdoors.
References	SPC accessed online 28/10/2019 CDF list 1.152 "Rubraca® dosing and adverse reaction management guide" clovis oncology

NB For funding information, refer to CDF and NICE Drugs Funding List

Repeat every 28 days: To start within 8 weeks of completing a minimum of 4 cycles of platinum-containing chemotherapy

TTO	Drug	Dose	Route	Directions
Day 1	**RUCAPARIB**	**600mg**	PO	BD (12 hours apart) Can be taken with or without food. Available as 200mg, 250mg and 300mg tablets. Dispense 30 days' supply.
	Metoclopramide	10mg	PO	TDS PRN Do not take for more than 5 days continuously. (dispense 28 tablets on cycle 1, then only if specified)