

Rota code: HROTA450

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Valid until: Next Review

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Clinical Nurse Specialist:

age: 1 of 3

Reference: ECHO trial, SmPC, EAMS document

University Hospitals Birmingham and Edgbaston

Ward/Unit:

MRN:

Name:

DOB:

Address:

NHS No:

Consultant:

Hb

WBC

Plt

Neuts

Na+

K+

Urea

Cr

GFR

Ca

Mg

Alb

AKP

ALT

Billi

TSH

T4

Cortisol

Height

Weight

BSA

Date

Allergies:

Recorded by

Date

Indication: Previously untreated Mantle Cell Lymphoma (consult eligibility/exclusion criteria for further information)

To be given every 28 days for up to 6 cycles, then to proceed to Acalabrutinib/Rituximab maintenance (HROTA 451)

Funding status: Bendamustine/Rituximab—Bluebird required

Acalabrutinib—Supplied Free of Charge from Astra Zeneca

Emetogenic potential: Moderately emetogenic

Extravasation classification: Bendamustine—Vesicant

Rituximab—Neutral

Hepatitis B Status:

Treatment intent: Disease Modification

Cycle frequency and duration: Every 28 days, up to 6 cycles

Cycle number:

Day No. Date	DRUG or ELECTRO-LYTE	CALCULATION	DOSE	IV FLUIDS	VOL. MLS.	ROUTE/FLOW RATE	SPECIAL DIRECTIONS/ ADMINISTRATION DETAILS	DRUG ADMINISTRATION	TIME	Pharmacy
1	Dexamethasone		8mg			Oral	1 hour before rituximab	Sig.		
1	Paracetamol		1000 mg			Oral	1 hour before rituximab			
1	Chlorphenamine		8mg			Oral	1 hour before rituximab			
1	RITUXIMAB (Rixathon)	375mg/m ²		Sodium Chloride 0.9%	500ml	IV Infusion—see below for rate				
1	Metoclopramide		10mg			Oral	To follow rituximab			
1	BENDAMUSTINE	90mg/m ²		Sodium Chloride 0.9%	500ml	IV Infusion over 30 mins				
2	Dexamethasone		8mg			Oral				
2	Metoclopramide		10mg			Oral				
2	BENDAMUSTINE	90mg/m ²		Sodium Chloride 0.9%	500ml	IV Infusion over 30 mins				

Prescriber sig: Name Date

Pharmacist initial sig: Name Date

Pharmacist final sig: Name Date

Nurse final auth sig: Name Date

University Hospitals Birmingham: Queen Elizabeth Hospital Birmingham, Mindelsohn Way Edgbaston, Birmingham B15 2GW

Acalabrutinib, Bendamustine and Rituximab for Mantle Cell Lymphoma (EAMS):

Other Information — Acalabrutinib

Haematology parameters and dose modifications: In case of grade 3 thrombocytopenia with bleeding, (platelets $25-50 \times 10^9/L$), grade 4 thrombocytopenia (platelets $< 25 \times 10^9/L$), or grade 4 neutropenia (Neuts $< 0.5 \times 10^9/L$) lasting longer than 7 days. First and second occurrence, interrupt treatment. When toxicity has resolved to grade 1 (Neuts $> 1.5 \times 10^9/L$, platelets $> 75 \times 10^9/L$), or baseline level, resume at 100mg BD. Third occurrence, interrupt treatment. Once toxicity has resolved to Grade 1 or baseline level, resumed at 100mg daily. Fourth occurrence, permanently discontinue treatment.

Toxicities and dose modifications: Acalabrutinib should be interrupted for a grade 3 or greater non-haematological toxicity. Once toxicity has resolved to baseline or grade 1, for the 1st/2nd occurrence restart acalabrutinib at 100mg BD, for the 3rd occurrence restart acalabrutinib at 100mg once daily. If it is the 4th occurrence discontinue acalabrutinib.

Drug interactions: Avoid co-administration with strong CYP3A inhibitors and inducers. Adverse effect monitoring recommended with concomitant moderate CYP3A inhibitors. Caution with anti-thrombotic agents—may require additional monitoring. Warfarin or other vitamin K antagonists should not be given concomitantly with Acalabrutinib.

Undesirable effects: Monitor for bleeding, and manage appropriately. Monitor patients for signs and symptoms of infection, and treat as needed. Other malignancies have occurred in patients, including skin cancers and other carcinomas. Advise patients to use sun protection. Monitor for atrial fibrillation and atrial flutter, and manage as appropriate.

Surgery: Consider the benefit-risk of withholding acalabrutinib for at least 3 days pre and post-surgery.

Rituximab Administration

First Infusion:
Initial rate of 50mg/hr for the first 30 minutes. Can then be escalated in 50mg/hr increments every 30 minutes, to a maximum rate of 400mg/hr.

Subsequent infusions:
If first infusion is well tolerated, the following rapid schedule can be used: give 100ml over 30 minutes. Then give remaining 400ml over 60 minutes.

In patients receiving the rapid infusion schedule, record all infusional toxicity on the appropriate form.

In the event of a slower infusion rate being required, use the following schedule: initial rate of 100mg/hr for the first 30 minutes. Can then be escalated in 100mg/hr increments every 30 minutes, to a maximum rate of 400mg/hr.

Fast infusion rate for patients who tolerate their first cycle – 20% of total dose given over 30 minutes and 80% of total dose over the following 60 minutes.

- Elderly patients or those with a high tumour burden may require a slower infusion rate.
- If a patient develops severe cytokine release syndrome the infusion should be interrupted immediately. On resolution, the infusion can be resumed at not more than one-half the previous rate. Mild to moderate infusion-related reactions usually respond to a reduction in infusion rate.
- During infusion, the patient's vital signs (BP, pulse, respiration and temperature) should be monitored every 15 minutes for the first hour, and then if stable, hourly until infusion stops.