

Rota code: HROTA450		Issue date: April 2025	Written by: Steve Hill	Authorised by: Shankara Panesha																	
Version no. 1.0		Valid until: Next Review	Checked by (Pharmacist): Djoumial Anstur	Clinical Nurse Specialist:																	
Acalabrutinib, Bendamustine and RituXimab for Mantle Cell Lymphoma (EAMS):																					
MRN:	Ward/Unit:	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">Hb</td><td style="width: 50%;">Na⁺</td></tr> <tr><td>WBC</td><td>K⁺</td></tr> <tr><td>Pt</td><td>Urea</td></tr> <tr><td>Neuts</td><td>Cr</td></tr> <tr><td colspan="2">GFR</td></tr> <tr><td colspan="2">Ca</td></tr> <tr><td colspan="2">T4</td></tr> <tr><td colspan="2">Cortisol</td></tr> </table>				Hb	Na ⁺	WBC	K ⁺	Pt	Urea	Neuts	Cr	GFR		Ca		T4		Cortisol	
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Name:	Consultant:	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">Alb</td><td style="width: 50%;">Weight</td></tr> <tr><td>AlP</td><td>BSA</td></tr> <tr><td>Alt</td><td>Date</td></tr> <tr><td>Bili</td><td>Allergies:</td></tr> </table>				Alb	Weight	AlP	BSA	Alt	Date	Bili	Allergies:								
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DOB:	NHS No:																				
Address:		Recorded by:	Date:																		
<p>Indication: Previously untreated Mantle Cell Lymphoma (consult eligibility/exclusion criteria for further information)</p> <p>To be given every 28 days for up to 6 cycles, then to proceed to Acalabrutinib/Rituximab maintenance (HROTA451)</p>																					
Day No.	Date	DRUG or ELECTROLYTE	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	500ml 0.9%	IV Infusion— see below for rate														
1		Metoclopramide		10mg			Oral	To follow rituximab													
1		BENDAMUSTINE	90mg/m ²		Sodium Chloride	500ml 0.9%	IV Infusion over 30 mins														
2		Dexamethasone		8mg			Oral														
2		Metoclopramide		10mg			Oral														
2		BENDAMUSTINE	90mg/m ²		Sodium Chloride	500ml 0.9%	IV Infusion over 30 mins														
<p>Prescriber sig:Name..... Date:</p> <p>Nurse final auth sig:Name..... Date:</p> <p>Pharmacist initial sig:Name..... Date:</p> <p>Pharmacist final sig:Name..... Date:</p> <p>University Hospitals Birmingham: Queen Elizabeth Hospital, Birmingham, Mindelsohn Way Edgbaston, Birmingham B15 2GW</p>																					

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

MRN:	Vard/Unit:	Proceed rules, valid within 96 hours:			
Name:	Drug	Neut	Platelets	Renal	Hepatic
DOB:	Rituximab	<1.0 x 10 ⁹ /L (<0.75 x 10 ⁹ /L with marrow involvement) - Contact prescriber	<50 x 10 ⁹ /L - contact prescriber	No dose adjustment required	No dose adjustment required
Address:	Bendamustine	<1.0 x 10 ⁹ /L (<0.75 x 10 ⁹ /L with marrow involvement) - Contact prescriber	<50 x 10 ⁹ /L - contact prescriber	No dose adjustment required	Bilirubin 21-51 µmol/L – Give 63mg/m ² (70% dose). Bilirubin >51 µmol/L – No data. Consultant decision. Consider 50mg/m ² .
NHS No:	Acalabrutinib	<0.5 x 10 ⁹ /L – see other information	<25 x 10 ⁹ /L (<50 x 10 ⁹ /L with concurrent bleeding) – see other information	CrCl >30ml/min – No dose adjustment recommended.	Child Pugh A/B or Bilirubin ≤ 63 µmol/L (≤3 x ULN) – No dose adjustment recommended.
				CrCl ≤ 30ml/min or dialysis – No data. Use if benefit outweighs risk.	Child Pugh C or Bilirubin > 63 µmol/L (>3 x ULN) – Not recommended

Day No.	DRUG	DOSE	ROUTE	SPECIAL DIRECTIONS/ADMINISTRATION DETAILS	QUANTITY	Dispensed by	Checked by
1	ACALABRUTINIB (CALQUENCE) Tablets (FOC)	100mg twice daily	ORAL	Take 12 hours apart. Swallow whole with water (with or without food) Do not break, crush or chew. Avoid grapefruit, and grapefruit juice.	C1-5: 28 days □ C6: 56 days □ (FOC stock)		

Anti-emetics	Medications to be prescribed on PICS						
Metoclopramide 10mg TDS PRN PO	• Allopurinol 300mg OD from D3 for cycle 1 only (not to be given on the same days as bendamustine)	• Aciclovir 400mg BD PO	• Co-trimoxazole 480mg BD M/W/F PO				

Prescriber sig: Name: Date: Pharmacist initial sig: Name: Date:
 Nurse final auth sig: Name: Date: Pharmacist final sig: Name: Date:

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 ($\text{Neuts} > 1.5 \times 10^9/L$, 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.