

Indication	Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with intermediate-2 or high-risk myelofibrosis.
Treatment Intent	Curative/ Non-curative/Remission
Frequency and number of cycles	Repeat every 28 days Continue until disease progression, unacceptable toxicity or patient choice. NB Treatment should be discontinued after 6 months if there has been no reduction in spleen size or improvement in symptoms.
Monitoring Parameters pre-treatment	<ul style="list-style-type: none"> • Check virology status prior to cycle 1. • BP should be checked at baseline and before each cycle. • FBC, Cr, U&E and LFTs should be monitored each cycle. • Starting dose and dose modification: <ul style="list-style-type: none"> ○ For patients with platelet count of $> 200 \times 10^9 / l$ the recommended starting dose is 20mg BD. ○ For patients with platelet count between $100 \times 10^9 / l$ and $200 \times 10^9 / l$ the starting dose is 15mg BD. ○ For patients with platelet count between $75 \times 10^9 / l$ and $<100 \times 10^9 / l$ the starting dose is 10mg BD. ○ The maximum starting dose for patients with platelet count between $50 \times 10^9 / l$ and $<75 \times 10^9 / l$ is 5mg BD and the patients should be titrated cautiously. ○ Treatment should be discontinued for platelet count less than $50 \times 10^9 / l$ or neutrophil count less than $0.5 \times 10^9 / l$ ○ Dose titration can be considered if efficacy insufficient and blood counts are adequate after the first 4 weeks of treatment and no more frequently than every 2 weeks thereafter. The patient's dose can be increased by a maximum of 5 mg twice daily, up to the maximum dose of 25 mg twice daily. ○ Dose modification may be required for patients developing anaemia. • Renal Impairment: No specific dose adjustment is needed in patients with mild or moderate renal impairment. In patients with severe renal impairment ($CrCl < 30 ml/min$) starting dose based on platelet count should be reduced by approximately 50%. • Hepatic Impairment: In patients with hepatic impairment the recommended starting dose based on platelet count should be reduced by approximately 50%. • Infections: <ul style="list-style-type: none"> ○ Serious bacterial, mycobacterial, fungal and viral infections have occurred in patients treated with ruxolitinib. Patients should be monitored for signs and symptoms of infection. ○ Tuberculosis - patients should be evaluated for active and latent tuberculosis due to reports of tuberculosis during treatment. ○ Clinicians should educate patients about early signs and symptoms of herpes zoster, advising that treatment should be sought as early as possible. • Progressive multifocal leukoencephalopathy (PML) has been reported in patients treated with ruxolitinib. If PML is suspected treatment should be suspended until PML has been excluded. • Common drug interactions (for comprehensive list refer to BNF/SPC): <ul style="list-style-type: none"> ○ The dose of Ruxolitinib should be reduced by approximately 50% when administered with strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin, erythromycin, voriconazole, posaconazole) or dual inhibitor CYP 2C9 and CYP 3A4 (e.g. fluconazole). Avoid the concomitant use of ruxolitinib with fluconazole doses greater than 200 mg daily.

Protocol No	HAEM-AML-020	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version	3	Written by	M.Archer
Supersedes version	2	Checked by	H.Paddock P.Chan
Date	29.04.2022	Authorising consultant (usually NOG Chair)	M.Aldouri

	<ul style="list-style-type: none"> ○ Increased haematological monitoring is required during concomitant administration of ruxolitinib with strong CYP3A4 inhibitors or dual inhibitors of CYP2C9 and CYP3A4 enzymes. ○ Consider increasing the dose of ruxolitinib according to response if patient also prescribed a strong CYP 3A4 inducer. ● If a dose is missed, the dose should be omitted and the patient should resume with the next dose at the next scheduled time. ● For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet and Macmillan information sheet. ● Dizziness has been reported as a side effect, if effected patients should refrain from driving or operating machinery.
References	SPC accessed online 03.02.2022 KMCC proforma HAEM-AML-020 V2 CDF list V1.201 accessed online 28.01.2022

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

Repeat every 28 days

TTO	Drug	Dose	Route	Directions
Day 1	RUXOLITINIB	15mg*	PO	Twice a day. (Available as 5mg, 10mg, 15mg and 20mg tablets)
*see notes above: starting dose dependant on PLT count.				

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