

Regimen Reference Order – HEME – fedratinib

ARIA: HEME - [fedratinib]

Planned Course: Once daily until disease progression or unacceptable toxicity (1 cycle = 30 days)

Indication for Use: Myelofibrosis

Proceed with treatment if:

ANC equal to or greater than $1 \times 10^9/L$ AND Platelets equal to or greater than $50 \times 10^9/L$

❖ **Contact Hematologist if parameters not met**

SEQUENCE OF MEDICATION ADMINISTRATION

Treatment Regimen – HEME – fedratinib

Drug	Dose	CCMB Administration Guideline
metoclopramide	10 mg	Orally once daily 30 minutes prior to fedratinib (Self-administered at home)
fedratinib	400 mg	Orally once daily with food Swallow whole (Self-administered at home)
fedratinib (INREBIC®) available dosage strength: 100 mg capsule Classification: Cytotoxic, Hazardous		

REQUIRED MONITORING

Baseline

- Hepatitis A, B and C and HIV serology

Cycles 1 to 3

- CBC, serum creatinine, urea, electrolytes, liver enzymes and total bilirubin as per Physician Orders
- Lipase once monthly as per Physician Orders

Cycle 4 and Onwards

- CBC, serum creatinine, urea, electrolytes, liver enzymes and total bilirubin as per Physician Orders
- Lipase once monthly as per Physician Orders

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
thiamine (vitamin B1)	100 mg	Orally once daily with food
metoclopramide	10 mg	Orally every 4 hours as needed for nausea and vomiting

INSTRUCTIONS FOR PATIENT

- Patients should report any signs/symptoms of encephalopathy (i.e. mental status changes, ataxia, visual disturbances, confusion, memory impairment)
 - If patient develops diarrhea, they should treat with antidiarrheal medications (e.g. loperamide) at first onset of symptoms. Contact clinic if diarrhea is not responsive to supportive care within 48 hours
 - fedratinib should be taken with food, preferably with a high-fat evening meal, to reduce nausea and vomiting
 - fedratinib has potential for drug-drug interactions. Patients should notify clinic prior to starting any new medication
 - Avoid grapefruit and grapefruit juice, Seville oranges (i.e. orange marmalade) and starfruit
 - Reinforce applicable safe handling precautions of medications, blood and body fluids for 48 hours after fedratinib
-

ADDITIONAL INFORMATION

- Do not initiate treatment with fedratinib in patients with thiamine deficiency; replete thiamine prior to treatment initiation
- fedratinib may cause serious and fatal encephalopathy including Wernicke's. If encephalopathy is suspected, fedratinib should be discontinued and parenteral thiamine should be initiated
- Support protocol is available under **[fedratinib]** in the "Hematology" folder
- fedratinib will be dispensed by CCMB Pharmacy