

Regimen Reference Order – THOR – osimertinib

ARIA: LUNG - [osimertinib (ADJ)]

LUNG - [osimertinib (MET)]

Planned Course: **Adjuvant:**
 Once daily until disease progression or unacceptable toxicity up to 3 years
 (1 cycle = 30 days)
 OR
Locally Advanced/Metastatic:
 Once daily until disease progression or unacceptable toxicity
 (1 cycle = 30 days)

Indication for Use: Non-Small Cell Lung Cancer EGFR Mutation-Positive

Proceed with treatment if:

- *ANC equal to or greater than $1 \times 10^9/L$ AND Platelets equal to or greater than $75 \times 10^9/L$*
- *AST/ALT less than 5 times upper limit of normal*
- *Total bilirubin less than 3 times upper limit of normal*
- ❖ **Contact Physician if parameters not met**

SEQUENCE OF MEDICATION ADMINISTRATION

Treatment Regimen – THOR – osimertinib

Drug	Dose	CCMB Administration Guideline
osimertinib	80 mg	Orally once daily with or without food Swallow whole (Self-administered at home)
osimertinib (TAGRISSO®) available dosage strengths: 40 mg and 80 mg tablets Classification: Cytotoxic, Hazardous		

REQUIRED MONITORING

Baseline and at every clinic visit (at least every 3 to 4 months)

- CBC, serum creatinine, urea, electrolytes (including potassium, calcium and magnesium), liver enzymes, total bilirubin and albumin as per Physician Orders
- Physical examination and chest x-ray as per Physician Orders

Cardiac Monitoring

- EKG
 - At baseline, then
 - 2 to 4 weeks after starting osimertinib, then
 - Every 3 to 4 months as per Physician Orders
- Monitor heart rate at each clinic visit
- LVEF monitoring is not required at baseline. If clinically indicated, cardiac investigations will occur at prescriber's discretion

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
loperamide	2 – 4 mg	Orally as directed below

INSTRUCTIONS FOR PATIENT

- Inform patient that any new/worsening cough or shortness of breath must be reported and assessed urgently by the medical oncologist or designate (i.e. family practitioner in oncology) because of the risk of interstitial lung disease/pneumonitis
- osimertinib can cause cutaneous and ocular toxicities. Patient should be instructed to notify clinic if they experience rash or eye problems
- Patients should be instructed to purchase loperamide at their retail pharmacy
- Patients should take loperamide 4 mg (two 2 mg tablets) if they have a loose bowel movement, followed by 2 mg (one 2 mg tablet) after each loose stool
 - Patients should not exceed a maximum of 16 mg (eight 2 mg tablets) in a 24-hour period
 - Patient should contact their cancer team if they have more than 3 loose bowel movements in a 24-hour period
- osimertinib 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 while on osimertinib treatment

ADDITIONAL INFORMATION

- osimertinib can cause QT prolongation
- osimertinib has been associated with left ventricular dysfunction and cardiomyopathy
- osimertinib will be dispensed by CCMB Pharmacy