

Regimen Reference Order

GENU – niraparib and abiraterone (AKEEGA) and predniSONE

ARIA: GENU – [niraparib-abiraterone (AKEEGA)]

Planned Course: Once daily until disease progression or unacceptable toxicity (1 cycle = 30 days)
Indication for Use: Metastatic castration-resistant prostate cancer (mCRPC); BRCA mutated

Proceed with treatment if:

- *ANC equal to or greater than $1 \times 10^9/L$ AND Platelets equal to or greater than $100 \times 10^9/L$*
 - *Total bilirubin equal to or less than 1.5 times the upper limit of normal*
 - *AST/ALT equal to or less than 3 times the upper limit of normal*
- ❖ **Contact Physician if parameters not met**

SEQUENCE OF MEDICATION ADMINISTRATION

Treatment Regimen – GENU – niraparib and abiraterone (AKEEGA) and predniSONE

| Drug | Dose | CCMB Administration Guideline |
|--|---|--|
| niraparib/abiraterone (combination tablet AKEEGA®) | 200 mg/1000 mg (2 of 100 mg/500 mg tablets) | Orally once daily on an empty stomach Swallow whole (Self-administered at home) |
| predniSONE | 10 mg | Orally once daily in the morning with food (Self-administered at home) |

niraparib and abiraterone combination (AKEEGA®) available dosage strengths: 100 mg/500 mg and 50 mg/500 mg tablets
Classification: Cytotoxic, Hazardous

REQUIRED MONITORING

Blood pressure and heart rate

- Weekly for cycles 1 and 2, then
- Monthly for 1 year, then
- As clinically indicated thereafter

Cycle 1

Day 1

- CBC, serum creatinine, urea electrolytes including magnesium and potassium, liver enzymes, total bilirubin, albumin, glucose, PSA and testosterone as per Physician Orders

Day 8

- CBC

Day 15

- CBC, electrolytes, liver enzymes and total bilirubin

Day 22

- CBC

Cycles 2 and 3

Day 1

- CBC, serum creatinine, urea electrolytes including magnesium and potassium, liver enzymes, total bilirubin, albumin, glucose, PSA and testosterone as per Physician Orders

Day 15

- CBC, liver enzymes, total bilirubin and electrolytes

Cycle 4 and onwards

- CBC, serum creatinine, urea electrolytes including magnesium and potassium, liver enzymes, total bilirubin, albumin, glucose, PSA and testosterone as per Physician Orders

Recommended Support Medications

| Drug | Dose | CCMB Administration Guideline |
|----------------|------------|--|
| metoclopramide | 10 – 20 mg | Orally every 4 hours as needed for nausea and vomiting |

DISCHARGE INSTRUCTIONS

- Patient should be reminded that AKEEGA® must be taken on an empty stomach. No solid or liquid food should be consumed for at least two hours before and at least one hour after AKEEGA® is taken. Do not crush or chew tablets
- AKEEGA® has potential for drug-drug interactions. Patients should notify clinic prior to starting any new medication
- predniSONE is a cancer therapy in this treatment regimen. Remind patient to take predniSONE at home
- Reinforce applicable safe handling precautions of medications, blood and body fluids while on AKEEGA®

ADDITIONAL INFORMATION

- Brand name AKEEGA® contains two drugs (niraparib and abiraterone) in one oral combination tablet
- Androgen Deprivation Therapy (ADT) (e.g. goserelin, leuprolide, degarelix) is continued lifelong throughout treatment course/lines of systemic therapy for prostate cancer
- abiraterone can prolong QT interval
- Cardiovascular events have been reported with AKEEGA®. AKEEGA® should be used with caution in patients with a history of cardiovascular disease
- AKEEGA® can cause hypertension hypokalemia and fluid retention due to mineralocorticoid excess
- AKEEGA® has been associated with significant anemia
- AKEEGA® can rarely cause Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML). Monitor for prolonged cytopenia