DRUG DIGEST

Bio Ascend™

Niraparib monotherapy for 1L maintenance ovarian cancer

VOLUME 1 MAINTENANCE

NURSING REFERENCE GUIDE

Indication: For the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy

Dosing: Niraparib – The starting dose is 300 mg PO daily.

- Expect to interrupt dose and modify in ~50% of patients in the first month to quickly achieve the optimal dose

Recommended Dose Modifications for Adverse Reactions[1]

Starting dose level	200 mg	300 mg
First dose reduction	100 mg/day* (one 100-mg capsule)	200 mg/day* (two 100-mg capsule)
Second dose reduction	Discontinue medication	100 mg/day* (one 100-mg capsule)

* If further dose reduction below 100 mg/day is required, discontinue Niraparib

1 STARTING DOSE

The recommended daily dose of niraparib is:
300 mg (three 100-mg tablets)
taken orally once daily, with or without food

WITH OR WITHOUT FOOD

100 mg + 100 mg + 100 mg = 300 mg DAILY

WEIGHTS AND PLATES DOSING

For patients weighing less than 77 kg (170 lbs)
OR with a platelet count of less than 150,000/µL
Recommended dose is 200 mg (two 100-mg capsules)
taken orally once daily

For patients weighing greater than or equal to 77 kg (170 lbs)
AND who have a platelet count greater than or equal to 150,000/µL
Recommended dose is 300 mg (three 100-mg capsules)
taken orally once daily

2 FIRST DOSE REDUCTION

After interruption and recovery
200 mg (two 100-mg tablets)
taken orally once daily, with or without food

WITH OR WITHOUT FOOD

100 mg + 100 mg = 200 mg DAILY

3 SECOND DOSE REDUCTION

After interruption and recovery
100 mg (one 100-mg tablet)
taken orally once daily, with or without food

WITH OR WITHOUT FOOD

100 mg = 100 mg DAILY

PATIENT MONITORING

Monitoring complete blood counts, blood pressure, and heart rate will help identify the need to dose modify

BLOOD COUNTS Your healthcare provider will do blood tests to check your blood cell counts:

1ST MONTH	REST OF YEAR	AS NEEDED DURING TREATMENT
ONCE WEEKLY 1 ONE MONTH	ONCE MONTHLY 11 ELEVEN MONTHS	ONE TIME 1 EVERY 2-3 MONTHS

BLOOD PRESSURE AND HEART RATE Your healthcare provider will check your blood pressure and heart rate:

1ST AND 2ND MONTH	REST OF YEAR	AS NEEDED DURING TREATMENT
ONCE WEEKLY	ONCE MONTHLY 10 TEN MONTHS	ONE TIME 1 EVERY 2-3 MONTHS

Discussion Points for Counseling Your Patients

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MDS/AML

Advise patients to contact their healthcare provider if they experience any of the symptoms listed below. This may be a sign of hematological toxicity or myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML) which has been reported in patients treated with niraparib

- Weakness
- Feeling tired
- Fever
- Weight loss
- Frequent infections
- Bruising
- Bleeding easily
- Breathlessness
- Blood in urine or stool
- And/or laboratory findings of low blood cell counts or a need for blood transfusions

Bone Marrow Suppression

Advise patients that periodic monitoring of their blood counts is required. Advise patients to contact their healthcare provider if they experience any of these symptoms

- New onset of bleeding
- Fever
- Symptoms of infection*

* Fever (this is sometimes the only sign of an infection) | Chills and sweats
Change in cough or a new cough | Sore throat or new mouth sore
Shortness of breath | Nasal congestion | Stiff neck | Burning or pain with urination

Cardiovascular Effects

Advise patients to undergo blood pressure and heart rate monitoring at least weekly for the first 2 months, then monthly for the first year of treatment, and then periodically thereafter

Advise patients to contact their healthcare provider if blood pressure is elevated

Dosing Instructions

Inform patients on how to take niraparib. Each capsule should be swallowed whole. Bedtime administration may be a potential method for managing nausea

Take with or without food

Take niraparib once daily

Do not take an extra dose to make up for the one you missed

If you miss a dose of niraparib, wait to take the next dose at the regularly scheduled time

Embryo-Fetal Toxicity

Advise females to inform their healthcare provider if they are pregnant or become pregnant

Inform female patients of the risk to a fetus and potential loss of the pregnancy

Contraception

Advise females of reproductive potential to use effective contraception during treatment with niraparib

Use effective contraception for at least 6 additional months after receiving the last dose

Lactation

Advise patients not to breastfeed while taking niraparib

Do not breastfeed for at least 1 additional month after receiving the last dose

REFERENCES

1. ZEJULA (niraparib). Prescribing Information. GlaxoSmithKline; 2020.
2. Centers for Disease Control. Know the signs and symptoms of infection. CDC website. https://www.cdc.gov/cancer/preventinfections/symptoms.htm. Accessed February 26, 2021.