

All-trans retinoic acid, Arsenic Trioxide, and Gemtuzumab oozogamicin for Acute Promyelocytic Leukemia molecular relapse or failure

Contact Physician: _____ **Pager:** _____

Diagnosis: _____ **CR date** _____

Consolidation: Week _____ **Consent form done**

Weight: _____ **Height:** _____ **BSA:** _____

Adjusted IBW: _____ **Adjusted BSA:** _____

Allergies: _____

Arsenic Trioxide 0.15mg/kg IV over one hour daily.

All-trans retinoic acid (ATRA) 45mg/m²/day PO in two divided doses.

Gemtuzumab oozogamicin 9mg/m² IV monthly for 3 months.

If repeat PCR becomes negative, repeat above regimen for additional 3months.

If repeat PCR remains positive, then substitute Idarubicin 12mg/m² IV daily for 3 days for the Gemtuzumab, give monthly for 3 months and continue ATRA and ATO.

1. Hydration:

2. Prophylactic medications:

- Acyclovir: 400mg PO twice daily
- Antifungal:
- GI prophylaxis:

3. Anti-emetics: (check the appropriate medications)

- Lorazepam: 0.5mg - 1 mg PO or IV every 4 hours prn nausea
- Prochlorperazine 10mg PO or IV every 6 hours prn nausea

4. Chemotherapy:

- **All-trans retinoic acid** (45mg/m²/day) _____mg PO in two divided doses daily rounded to the nearest 10mg, _____ mg every morning and _____mg every evening.
Tablet size 10mg.

- **Arsenic trioxide** (0.15mg/kg) _____mg in Sodium Chloride 0.9% 250mL IV over one hour daily. (Alternate: May consider giving 5 days/week, Monday-Friday.)
Arsenic trioxide _____ mg IV over one hour on _____.
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- Gemtuzumab ozogamicin** (9mg/m²) _____mg in Sodium Chloride 0.9% 100mL IV over 2 hours monthly for 3 months. Dose 1_____, Dose 2_____, Dose 3 _____. Infuse gemtuzumab through a separate IV line with low protein-binding 0.22 micron terminal filter.

Pre-Medications:

- Diphenhydramine: 50 mg PO 1 hour prior to gemtuzumab ozogamicin and 4 and 8 hours post gemtuzumab ozogamicin.
- Methylprednisolone: 50mg IV 1 hour prior to and 1 hour into the infusion of gemtuzumab ozogamicin.
- Acetaminophen 650 mg PO 1 hour prior to gemtuzumab ozogamicin and 4 and 8 hours post gemtuzumab ozogamicin

Monitor vital signs every ½ hour during infusion.

Signed: _____ Pager: _____

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Addendum: Recommended monitoring and dose reductions

All trans retinoic acid:

- For grades 3&4 toxicity (headaches, rash) reduce dose by 50%. Discontinue if toxicity persists after dose reduction.

Arsenic trioxide:

Dose reductions:

- For peripheral neuropathy or arrhythmias, dose reduce or discontinue.
- Signs and symptoms of toxicity (convulsions, muscle weakness, confusion) require immediate discontinuation of arsenic trioxide therapy and consideration of chelation therapy (dimercaprol 3mg/kg intramuscularly every 4 hours until life threatening toxicity has subsided and may be followed by penicillamine 250mg orally up to 4 times daily).

Monitoring parameters:

- Prior to initiating therapy serum electrolytes (potassium, calcium, and magnesium) and creatinine should be assessed; pre-existing abnormalities should be corrected
- Prior to initiating therapy, a 12 lead electrocardiogram (ECG) should be performed. QT intervals greater than 500milliseconds should be corrected and reassessed with serial ECGs prior to considering therapy.
- During therapy, hematologic, electrolyte, and coagulation profiles should be monitored twice weekly during the induction phase (more frequently for clinically unstable patients) and at least weekly during the consolidation phase. Potassium concentrations should be kept above 4mEq/dL and magnesium concentrations should be kept above 1.8mEq/dL.
- During induction and consolidation, ECGs should be obtained weekly (more frequently for clinically unstable patients). Patients with QT intervals that exceed 500milliseconds during therapy require action to correct concomitant risk factors and assessment of risk/benefit of continuing therapy.

Reference: Product information

