VANCOUVER HOSPITAL & HEALTH SCIENCES CENTRE
CSU PHARMACEUTICAL SCIENCES
INVESTIGATIONAL DRUG DATA SHEET

DRUG NAME
Gemtuzumab ozogamicin

ALTERNATE NAME
Mylotarg™

MANUFACTURER
Wyeth-Ayerst Pharmaceuticals, Inc.

STRENGTH
5mg, 20mL vial

DOSAGE FORM
Injection

INDICATIONS
- chemotherapy agent composed of a recombinant humanized IgG4, kappa antibody conjugated with a cytotoxic antitumour antibiotic, calicheamicin
- the antibody portion binds to the CD33 antigen on the surface of leukemic blasts and immature normal cells of myelomonocytic lineage, but not normal hematopoietic stem cells
- for the treatment of patients with CD33 positive acute myeloid leukaemia in first relapse who are 60 years of age or older and who are not candidates for other cytotoxic chemotherapy

DOSAGE AND ADMINISTRATION
- recommended dose is 9mg/m^2, administered as a 2-hour intravenous infusion peripherally or via a central line
- infuse using a separate IV line equipped with a low protein-binding 1.2-micron terminal filter (Baxter 2C1103)
- treatment course is a total of 2 doses with 14 days between the doses
- DO NOT ADMINISTER AS AN INTRAVENOUS BOLUS OR PUSH
- protect from direct and indirect sunlight during administration

KNOWN SIDE EFFECTS*
- infusion reactions include fevers and chills, and less commonly hypotension and dyspnea that may occur during the first 24 hours after administration
- severe myelosuppression will occur in all patients (careful hematologic monitoring is required)
- infrequently, fatal hypersensitivity reactions, pulmonary events, and hepatotoxicity have been reported; opportunistic infections may also occur

SPECIAL PRECAUTIONS
- keep drug refrigerated at 2-8 C
- Drug preparation
  - prior to reconstitution, allow drug vials to come to room temperature
  - protect from unshielded fluorescent light during preparation (all preparation be in a biologic safety hood with the fluorescent light off)
  - reconstitute with 5mL sterile water and gently swirl vial
  - (reconstituted drug may be stored in the vial refrigerated at 2-8 C and protected from light for up to 8 hours)
  - withdraw the desired volume from each vial, and inject into a 100mL IV bag of NS
  - place into an UV protectant bag
  - Absolute expiry of drug in 100 ml NS bag = 18 hours at room temperature. (With UV protection)
  - use the resulting drug solution immediately
- contraindicated in known hypersensitivity to gemtuzumab and any of its components
- patients should receive pre-medications: diphenhydramine 50mg PO and acetaminophen 650-1000mg PO; thereafter, two additional doses of acetaminophen 650-1000mg PO, every 4 hours as needed
- infusion should be interrupted in patients with dyspnea or clinically significant hypotension
- monitor vital signs prior to, during, and for 4 hours after the infusion
- electrolytes, hepatic function, complete blood counts, and platelet counts should be monitored

***REPORT ANY ADVERSE DRUG REACTIONS TO THE PHARMACY**