

**VANCOUVER HOSPITAL & HEALTH SCIENCES CENTRE
PHARMACY SERVICES
INVESTIGATIONAL DRUG DATA SHEET**

DRUG NAME

Granulocyte-Macrophage Colony-Stimulating Factor
GM-CSF
Sargramostim

ALTERNATE NAME

Leucotropin[®] (Cangene)
Leukine[®] (Berlex)

MANUFACTURER

Cangene Corp.
Berlex Laboratories, Inc.

STRENGTH

Leucotropin[®] (Cangene) 500µg vial
Leukine[®] (Berlex) 500µg/mL vial

DOSAGE FORM

lyophilized powder for reconstitution
liquid for injection

INDICATIONS

- To stimulate the function and proliferation of granulocytes and macrophages
- To treat refractory hemorrhagic cystitis in patients who have undergone a BMT (experimental)
- Neutrophil Recovery post chemo in AML, Mobilization of peripheral blood progenitor cells, post peripheral blood progenitor cell transplantation, Myeloid reconstitution after BMT, BMT failure or Engraftment delay.
- Produced by recombinant human DNA technology

DOSAGE AND ADMINISTRATION

- 250µg/m²/day administered IV over 2-24 hours or SC daily. Duration of therapy dependent on protocol.
- Refractory Hemorrhagic Cystitis in BMT patients: 400µg diluted in 200mL normal saline allowed to rest for 60-120 minutes. Treat daily for 3 consecutive days (experimental use). After treatment, continue continuous bladder irrigation.

KNOWN SIDE EFFECTS*

- Fever, chills, asthenia, headache, malaise, abdominal pain, chest pain, flu-like syndrome, rash
- Bone pain, myalgia, arthralgia
- Peripheral edema, pleural and/or pericardial effusion, dyspnea
- Diarrhea, nausea, and vomiting
- Elevation of serum creatinine or bilirubin and hepatic enzymes
- Tachycardia

SPECIAL PRECAUTIONS

- store vials in refrigerator (2-8 degrees C)
- dilute in Normal Saline only
- use in caution in patients with pre-existing fluid retention, pulmonary infiltrates, CHF, hypoxia, and cardiac disease
- in patients with renal or hepatic dysfunction prior to treatment, renal and hepatic function should be monitored at least every two weeks.

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