VANCOUVER HOSPITAL & HEALTH SCIENCES CENTRE
PHARMACY SERVICES
SPECIAL ACCESS PROGRAMME DRUG DATA SHEET

DRUG NAME
Sargramostim

ALTERNATE NAMES
Leukine®, GM-CSF
Granulocyte-Macrophage Colony-Stimulating Factor

MANUFACTURER
Sanofi Aventis

STRENGTH
250 mcg vial

DOSAGE FORM
Lyophilized powder for reconstitution

INDICATIONS
- To stimulate the function and proliferation of granulocytes and macrophages (various indications)

DOSAGE AND ADMINISTRATION
- 250 mg/m^2/day administered IV over 2-24 hours or SC DAILY. Duration of therapy dependent on protocol.

KNOWN SIDE EFFECTS*
- Fever, chills, allergic reactions, asthenia, headache, malaise, abdominal pain, chest pain, flu-like syndrome, rash, bone pain, myalgia, arthralgia, peripheral edema, capilliary leak syndrome, pleural and/or pericardial effusion, dyspnea, diarrhea, nausea, and vomiting, arrhythmia, tachycardia, fainting, eosinophilia, dizziness, hypotension, injection site reactions, pain, thrombosis and transient liver function abnormalities. (Refer to product monograph for complete list)

SPECIAL PRECAUTIONS
- Store vials in refrigerator (2-8 degrees C)
- Reconstitute the 250 mcg vial with 1 mL sterile water for injection. Direct the stream of sterile water to the side of the vial. Swirl gently to reconstitute. Do NOT shake the vial.
  Expiry 6 hours (refrigerate).
- For IV use dilute in sodium chloride 0.9% solutions only. Concentration should be 10 mcg/mL or above. For concentrations less than 10 mcg/mL, refer to the product monograph for instructions for adding albumin.
- Contraindicated
  In patients with excessive leukemic myeloid blasts in the bone morrow or peripheral blood
  In patients with known hypersensitivity to this product or any component of this product
  Given simultaneously with chemotherapy and radiotherapy.
- Use in caution in patients with pre-existing fluid retention, pulmonary infiltrates, and congestive heart failure, cardiac disease, hypoxia
- In patients with prexisting edema, capilliary leak syndrome, pleural and/or pericardial effusion, administration may aggravate fluid retention. Body weight and hydration status should be carefully monitored.
- In patients with renal or hepatic dysfunction prior to treatment, renal and hepatic function should be monitored at least every two weeks.
- Monitor CBC with differential twice weekly to preclude development of excessive counts.
- This data sheet is just a summary. Refer to the product monograph for more detailed information.
- Sargramostim is not available on the Canadian Market. Approval must be obtained from the Health Canada Special Access Programme prior to use.

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