CARSTIM: Carmustine Injection IP 100 mg

Indication: As a palliative therapy as a single agent or in combination therapy with other approved chemotherapeutic agents for: Brain tumors - glioblastoma, brainstem glioma, medulloblastoma, astrocytoma, ependymoma, and metastatic brain tumors; Multiple myeloma; Hodgkin's disease as secondary therapy and non-Hodgkin's lymphoma as secondary therapy. **Dosage and administration:** As a single agent in previously untreated patients: 150 – 200 mg/m^2 IV every 6 weeks. When used in combination with other myelosuppressive drugs/in patients in whom bone marrow reserve is depleted, adjust dose accordingly. Doses subsequent to the initial dose should be adjusted according to the hematologic response of the patient to the preceding dose. Evaluate renal function prior to administration and periodically during treatment. Discontinue carmustine powder for concentrate for solution for infusion if the creatinine clearance is less than 10 mL/min. **Contraindications:** In patients who have demonstrated a previous hypersensitivity to it. **Warning and precautions:** Include but are not limited to myelosuppression, pulmonary toxicity, administration reactions, carcinogenicity, ocular toxicity and embryo-fetal toxicity. **Drug interactions:** Coadministration of oral cimetidine with carmustine causes greater myelosuppression. Phenobarbital induces the metabolism of carmustine and may compromise antitumor activity of Carmustine powder for concentrate for solution for infusion. **Usage in pregnancy and lactation:** Safe use in pregnancy has not been established and therefore the benefit to risk of toxicity must be carefully weighed, Breast-feeding should not be permitted during the treatment. **Adverse effects:** Include but are not limited to serious adverse reactions like myelosuppression, pulmonary toxicity, administration reactions, carcinogenicity and ocular toxicity. Others include tachycardia, conjunctival haemorrhage, blurred vision, nausea, vomiting, anorexia, diarrhea, hepatotoxicity, nephrotoxicity and infections. **Storage:** At refrigerated condition between 2°C to 8°C, protected from light and moisture. Do not freeze. **Shelf-life:** 24 months.

For detailed information refer to the product information sheet.

Flu-Stim: Fludarabine 50mg Pack Insert DOM.

Indication: indicated for the treatment of adult patients with B-cell chronic lymphocytic leukemia (CLL) who have not responded to or whose disease has progressed during treatment with at least one standard alkylating-agent containing regimen. **Dosage and administration:** 25 mg/m^2 diluted in 100 to 125 cc of 5% dextrose injection USP or 0.9% sodium chloride USP administered intravenously over a period of approximately 30 minutes daily for five consecutive days**. Contraindications:** In those patients who are hypersensitive to this drug or its components. **Warnings and precautions:** Fludarabine may cause the following: neurotoxicity (Dose dependent toxic effects), haematological adverse reactions (severe bone marrow suppression, anaemia, neutropenia and thrombocytopenia), infections, tumor lysis syndrome and renal impairment (administer with caution in patients with renal impairment). **Drug interactions:** Use of fludarabine in combination with pentostatin is not recommended due to risk of severe pulmonary toxicity. **Usage in pregnancy and lactation:** Pregnancy Category D**,** may cause fetal harm when administered to a pregnant woman. **Adverse effects:** Include but are not limited to, the most common adverse reactions such as myelosuppression (neutropenia, thrombocytopenia and anemia), fever and chills, infections, and nausea and vomiting. Other common reactions include malaise, fatigue, anorexia, weakness, agitation, confusion, visual differences and coma. **Storage:** at refrigerated condition between 2° C to 8° C, protected from light and moisture. Do not freeze. **Shelf-life:** 24 months.

For detailed information refer to the product information sheet.

Mostim: Plerixafor Injection 24 mg/1.2mL

Indication: Plerixafor Injection is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM). **Dosage and administration:** Recommended dose of Mostim by subcutaneous injection is based on body weight: 20 mg fixed dose or 0.24 mg/kg of body weight for patients with body weight ≤ 83 kg. For patients with body weight > 83 kg, 0.24 mg/kg of body weight. Reduce the dose of Mostim by one-third in patients with moderate to severe renal impairment (CLCR ≤ 50 mL/min). The dose should not exceed 27 mg/day if CLCR ≤ 50 mL/min. **Contraindications:** contraindicated in patients with a history of hypersensitivity to plerixafor or if Anaphylactic shock has occurred with use of Mostim. **Precautions and warnings:** Include but are not limited to anaphylactic shock and hypersensitivity reactions, tumor cell mobilization in leukemia patients when used in combination with G-CSF and hematologic effects such as leukocytosis and thrombocytopenia. **Drug interactions:** No interaction studies have been performed. In vitro tests showed that Plerixafor was not metabolised by P450 CYP enzymes. **Usage in pregnancy, lactation and children:** Limited data available for use in pregnant women, advise pregnant women of the potential risk to the fetus. Breastfeeding is not recommended during treatment with Mostim and for one week after the final dose. The safety and effectiveness of Mostim have not been established in pediatric patients. **Storage:** Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F). **Shelf-life:** 24 months.

For detailed information refer to the product information sheet.

Synstim: Melphalan 50 mg

Indications: Melphalan Hydrochloride for Injection is indicated for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate. **Dosage and administration:** The usual IV dose is 16 mg/m^2, as single infusion over 15 to 20 minutes. In patients with renal insufficiency (BUN ≥ 30 mg/dL), reduce the dosage by 50%. For oral melphalan, repeated courses should be given since improvement may continue slowly over many months. **Contraindication:** Should not be used in patients whose disease has demonstrated prior resistance to this agent. Patients who have demonstrated hypersensitivity to melphalan should not be given the drug. **Precautions and warnings:** It may cause local tissue damage, thus should not directly be administered into peripheral vein. It is recommended for melphalan hydrochloride injection to be administered by injecting slowly into a fast-running IV infusion. It also causes a marked bone marrow suppression with excessive dosage. Withdraw therapy in case of thrombocytopenia and/or leukopenia. It should be used with extreme caution in patients with compromised bone marrow reserves. It may also cause carcinogenesis, mutagenesis and impairment of fertility. **Drug interactions:** Development of severe renal failure in patients treated with a single dose IV melphalan followed by cyclosporin standard oral dose. Nalidixic acid when given simultaneously with IV melphalan leads to incidence of severe haemorrhagic necrotic enterocolitis in paediatric patients. Cisplatin alters melphalan clearance by inducing renal dysfunction. **Usage in pregnancy, lactation and children:** Pregnancy category D, no adequate and well-controlled studies in pregnant women, thus the patient should be apprised of potential risk to the fetus. Should not be given in lactating mothers. The safety and effectiveness in pediatric patients have not been established. **Adverse effects:** Include but are not limited to bone marrow suppression, nausea, vomiting, diarhhea, oral ulceration, hypersensitivity reactions like anaphylaxis, skin hypersensitivity, maculopapular rashes, vasculitis, alopecia, hemolytic anemia and pulmonary fibrosis. **Storage:** at a temperature not exceeding 30°C, protected from light and moisture. Do not refrigerate. **Shelf-life:** 24 months.

For detailed information refer to the product information sheet.

Tepastim: Thiotepa Injection IP 15 mg/100 mg

Indications: As conditioning treatment prior to allogenic or autologous hematopoietic progenitor cell transplantation (HPCT) in haematological disease in adult and pediatrics patients, when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumors in adult and pediatrics patients. **Dosage and administration:** *Class 3 Beta-Thalassemia*: two administrations of 5 mg/kg given intravenously approximately 12 hours apart on Day -6 before allogeneic HSCT in conjunction with high-dose Busulfan and cyclophosphamide. *Adenocarcinoma of the Breast or Ovary:* 0.3 to 0.4 mg/kg intravenously, doses should be given at 1 to 4 week intervals. *Malignant Effusions:* 0.6 to 0.8 mg/kg intracavitary, doses should be given at 1 to 4 week intervals. *Superficial Papillary Carcinoma of the Urinary Bladder*: 60 mg in 30 to 60 mL of Sodium Chloride Injection into the bladder by catheter. The solution should be retained for 2 hours. Monitor patients with moderate to severe renal impairment and hepatic impairment for signs and symptoms of toxicity. **Contraindications:** In patients with severe hypersensitivity to thiotepa and concomitant use with live or attenuated vaccines. **Precautions and warnings:** Thiotepa injection may cause myelosuppression, hypersensitivity reactions, cutaneous toxicity, hepatic veno-occlusive disease, central nervous system toxicity, carcinogenicity and embryo-fetal toxicity. **Drug interactions:** Include but are not limited to: strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin, ritonavir) and strong CYP3A4 inducers (e.g., rifampin, phenytoin) when co administered with thiotepa effects the efficacy of thiotepa and may cause toxicity. **Usage in pregnancy:** no adequate and well-controlled studies of Thiotepa in pregnant women, advise pregnant women of the potential risk to the fetus. **Adverse effects:** Include but are not limited to fatigue, weakness, nausea, vomiting, abdominal pain, anorexia, dysuria, prolonged apnea, dizziness, headache, dermatitis and alopecia. **Storage:** Store unopened vial and transport refrigerated between 2°C to 8°C. Do not freeze. After reconstitution, use within 8 hours when stored in a refrigerator. After dilution, use within 24 hours when stored in a refrigerator. **Shelf-life:** 24 months.

For detailed information refer to the product information sheet.