Carmustine medac 100 mg powder and solvent for concentrate for solution for infusion
Qualitative and quantitative composition: Each vial of powder for concentrate for solution for infusion contains 100 mg carmustine. After reconstitution and dilution, one mL of solution contains 3.3 mg carmustine. *Excipient:* Each ampoule of solvent contains 3 ml ethanol anhydrous (equivalent to 2.37 g). **Therapeutic indications:** Carmustine is indicated in adults in the following malignant neoplasms as a single agent or in combination with other antineoplastic agents and/or other therapeutic measures (radiotherapy, surgery): Brain tumors (glioblastoma, Brain-stem gliomas, medulloblastoma, astrocytoma, ependymoma), brain metastases; secondary therapy in non-Hodgkin's lymphoma and Hodgkin's disease; tumours of the gastrointestinal tract; malignant melanoma in combination with other antineoplastic medicinal products; as conditioning treatment prior to autologous haematopoietic progenitor cell transplantation (HPCT) in malignant haematological diseases (Hodgkin's disease / Non-hodgkin's lymphoma). **Posology and method of administration:** The recommended dose of Carmustine as single agent in previously untreated patients is 150 to 200 mg/m^2 intravenously every 6 weeks. This may be given as a single dose or divided into daily infusions such as 75 to 100 mg/m^2 on two successive days. When used in combination with other myelosuppressive medicinal products or in patients in whom bone marrow reserve is depleted, doses should be adjusted according to the hematologic profile of the patient. Carmustine is given in combination with other chemotherapeutic agents in patients with malignant haematological diseases before HPCT at a dose of 300 - 600 mg/ m^2 intravenously. **Contraindications:** Hypersensitivity to the active substance, to other nitrosoureas or to any of the excipients; severe bone marrow depression; severe (end-stage) renal impairment; children and adolescents; breast-feeding. **Undesirable effects:** *Infections, infestations:* Opportunistic infections, including fatal (frequency not known). *Neoplasm:* Commonly acute leukemia, bone marrow dysplasia following long-term use. *Blood, lymphatic system:* Very commonly myelosuppression. Commonly anemia. *Nervous system:* Very commonly ataxia, dizziness, headache. Commonly encephalopathy (high-dose therapy and dose-limiting). Muscular pain, status epilepticus, seizure, grand mal seizure (frequency not known). *Eye:* Very commonly ocular toxicities, transient conjunctival, flushing, blurred vision due to retinal haemorrhages. *Cardiac:* Very commonly hypotension, due to the alcohol content of the solvent (high-dose therapy). Tachycardia (frequency not known). *Vascular:* Very commonly phlebitis. Rarely veno-occlusive disease (high-dose therapy). *Respiratory, thoracic, mediastinal:* Very commonly pulmonary toxicity, interstitial fibrosis with prolonged therapy and cumulative dose); pneumonitis. Rarely interstitial fibrosis (with lower doses). *Gastrointestinal:* Very commonly emetogenic potential; nausea and vomiting (severe). Commonly anorexia, constipation, diarrhea, stomatitis. *Hepatobiliary:* Commonly hepatotoxicity, reversible, delayed up to 60 days after administration (high-dose therapy and dose-limiting), manifested by reversible increase of bilirubin, alkaline phosphatase, SGOT. *Skin, subcutaneous tissue:* Very commonly dermatitis with topical use improves with reduced concentration of compounded product, hyperpigmentation, transient, with accidental skin contact. Commonly alopecia, flushing (due to alcohol content of solvent; increased with administration times <1-2 h), injection site reaction. Extravasation hazard vesicant (frequency not known). *Renal, urinary:* Rarely renal toxicity. *Reproductive system, breast:* Rarely gynecomastia. Infertility, teratogenesis (frequency not known). *Metabolism, nutrition:* Electrolyte abnormalities (hypokalemia, hypomagnesemia, hypophosphatemia) (frequency not known). **Legal classification**: POM (prescription only medicine). **Marketing authorisation holder:** medac GmbH, Theaterstraße 6; 22880 Wedel, Germany. **Date of revision of text**: 08/2024
Carmustine medac has been authorised in all countries of the EU as well as in Iceland, Norway, Liechtenstein, United Kingdom