Lomustine medac 40 mg hard capsules
Qualitative and quantitative composition: One capsule contains lomustine 40 mg. *Excipients:* Anhydrous lactose, wheat starch, talc, magnesium stearate; gelatin, titanium dioxide E171, indigo carmine E132. **Therapeutic indications:** As palliative or supplementary treatment, usually in combination with radiotherapy and/or surgery as part of multiple drug regimens in brain tumours (primary or metastatic), small cell lung cancer, Hodgkin's disease (resistant to conventional combination chemotherapy), malignant melanoma (metastatic), Non-Hodgkin lymphoma. **Posology and method of administration:** The recommended dose in patients with normally functioning bone marrow receiving Lomustine as their only chemotherapy is 120-130 mg/m² as a single dose every 6 to 8 weeks (or as a divided dose over 3 days, e.g. 40 mg/m²/day). The dose must not exceed 130 mg/m². In individuals with compromised bone marrow function, the dose should be reduced to 100 mg/m². Lomustine medac is given orally. The capsules should preferably be taken at bedtime or 3 hours after meals. **Contraindications:** Hypersensitivity to the active substance(s) or to any of the excipients; previous failure of the tumour to respond to other nitrosoureas; severe bone-marrow depression or renal impairment; coeliac disease or wheat allergy; concomitant use of yellow fever vaccine or other live vaccines in immunosuppressed patients: pregnancy, breast feeding. **Undesirable effects:** *Neoplasms:* Very rarely secondary malignancies. Acute leukaemia, myelodysplastic syndrome (frequency not known). *Blood and lymphatic system:* Very commonly bone marrow depression, like thrombocytopenia, leukopenia, neutropenia, anaemia. The most frequent and most serious toxicity of lomustine is delayed myelosuppression, often of a prolonged nature. *Nervous system:* Uncommonly apathy, disorientation, confusion, stuttering (in combination therapy). Coordination abnormal, lethargy, dysarthria (frequency not known). *Eye:* Very rarely irreversible vision loss after combined therapy with radiation. *Respiratory*, *thoracic, mediastinal:* Rarely lung fibrosis, interstitial pneumonia. Lung infiltration (frequency not known). *Gastrointestinal:* Very commonly nausea, vomiting, anorexia. Commonly stomatitis, diarrhoea. *Hepatobiliary:* Commonly disorders of liver function (mostly mild), transient elevation of liver enzymes (ASAT, ALAT, LDH, alkaline phosphatase). Rarely cholestatic jaundice. *Skin, subcutaneous tissue:* Very rarely alopecia. *Renal, urinary:* Very rarely renal failure. Azotaemia, renal atrophy, renal injury (frequency not known). *Investigations:* Blood bilirubin increased (frequency not known). **Legal classification:** POM (prescription only medicine). **Marketing authorization holder:** medac GmbH, Theaterstraße 6; 22880 Wedel, Germany. **Date of revision of text**: 01/2024
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