Spectrila® 10,000 U powder for concentrate for solution for infusion
Qualitative and quantitative composition: Each vial contains 10,000 units of asparaginase produced in *Escherichia coli* cells by recombinant DNA technology. One unit (U) is defined as the quantity of enzyme required to liberate one µmol ammonia per minute at pH 7.3 and 37°C. After reconstitution each ml contains 2,500 units of asparaginase. *Excipient:* Sucrose. **Therapeutic indications:** As a component of antineoplastic combination therapy for the treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years and adults. **Posology and method of administration:** Spectrila is usually employed as part of combination chemotherapy protocols with other antineoplastic agents. *Adults and children older than 1 year:* The recommended intravenous dose of asparaginase is 5,000 (U/m²) BSA given every third day. Treatment may be monitored based on the trough serum asparaginase activity measured three days after administration. If asparaginase activity values fail to reach target levels, a switch to a different asparaginase preparation could be considered. *Children 0– 12 months old:* Based on limited data, the recommended dose is: age less than 6 months 6,700 U/m² BSA; age 6– 12 months 7,500 U/m² BSA. For administration by intravenous infusion only. **Contraindications:** Hypersensitivity to the active substance, any native (non-pegylated) E. coli-asparaginase preparation or to the excipient; pancreatitis; severe hepatic impairment (bilirubin > 3 times ULN; transaminases > 10 times ULN); pre-existing known coagulopathy (e.g. haemophilia); history of pancreatitis, serious haemorrhage or serious thrombosis with prior asparaginase therapy. **Undesirable effects:** *Infections, infestations:* Infections (frequency not known). *Blood, lymphatic system:* Commonly disseminated intravascular coagulation (DIC), anaemia, leukopenia, thrombocytopenia. *Immune system:* Very commonly hypersensitivity including flushing, rash, hypotension, oedema/angioedema, urticaria, dyspnoea. Commonly hypersensitivity including bronchospasm. Rarely anaphylactic shock. *Endocrine:* Very rarely secondary hypothyroidism, hypoparathyroidism. *Metabolism, nutrition:* Very commonly hyperglycaemia, hypoalbuminaemia. Commonly hypoglycaemia, decreased appetite, weight loss. Uncommonly hyperuricaemia, hyperammonaemia. Rarely diabetic ketoacidosis. *Psychiatric:* Commonly depression, hallucination, confusion. *Nervous system:* Commonly neurological signs and symptoms including agitation, dizziness and somnolence. Uncommonly headaches. Rarely ischaemic stroke, reversible posterior leukoencephalopathy syndrome (RPLS), convulsion, disturbances in consciousness including coma. Very rarely tremor. *Vascular:* Commonly thrombosis especially cavernous sinus thrombosis or deep vein thrombosis, haemorrhage. *Gastrointestinal:* Very common diarrhoea, nausea, vomiting, abdominal pain. Commonly acute pancreatitis. Rarely haemorrhagic pancreatitis, necrotising pancreatitis, parotitis. Very rarely pancreatitis with fatal outcome, pancreatic pseudocyst. *Hepatobiliary:* Rarely hepatic failure with potentially fatal outcome, hepatic necrosis, cholestasis, jaundice. Hepatic steatosis (frequency not known). *General, administration site:* Very commonly oedema, fatigue. Commonly pain (back pain, joint pain). *Investigations:* Very commonly increase in transaminases, blood bilirubin, blood alkaline phosphatase, blood cholesterol, blood triglyceride, very low density lipoprotein (VLDL), lipoprotein lipase activity, blood urea, ammonia, blood lactate dehydrogenase (LDH), decrease in antithrombin III, blood fibrinogen, blood cholesterol, low density lipoprotein (LDL), total protein. Commonly increase in amylase, lipase, abnormal electroencephalogram (EEG) (reduced alpha wave activity, increased theta and delta wave activity). **Legal classification**: POM (prescription only medicine). **Marketing authorisation holder:** medac GmbH, Theaterstraße 6; 22880 Wedel, Germany. **Date of revision of text**: 03/2023
Spectrila has been authorised in all countries of the EU as well as in Iceland, Kazakhstan, Liechtenstein, Norway, United Kingdom