Bleomedac / Bleomycin medac 15000 IU (Ph. Eur.), powder for solution for injection
Qualitative and quantitative composition: One vial of 10 ml contains 15000 IU of bleomycin (as bleomycin sulphate). 1 mg of dry weight of the powder is equivalent to at least 1500 IU (Ph.Eur.). 1 U (USP) is equivalent to 1000 IU (Ph. Eur.) *Excipients:* None. **Therapeutic indications:** In combination with other cytostatic drugs and/or radiation therapy: Squamous cell carcinoma (SCC) of the head and neck, external genitalia and cervix; Hodgkin's lymphoma; Non-Hodgkin's lymphoma of intermediate and high malignancy in adults; testis carcinoma (seminoma and non-seminoma); intrapleural therapy of malignant pleural effusion. **Posology and method of administration:** *Warning:* Posology for all therapeutic indications is provided in IU and not in mg. Some protocols may state use "mg" instead of Units. This mg value refers to mg-activity and not to mg-dry material as these reflect different values. Bleomycin may be administered intravenously, intramuscularly, intrapleurally, intraperitoneally, intraarterially or subcutaneously. Local injection directly into the tumour may occasionally be indicated. Dose and intervals between injections are dependent on the indication, the method of administration, age and condition of the patient. The total dose of bleomycin in elderly patients should be reduced (see summary of product information). Administration of bleomycin in children should only take place in exceptional cases and in special centres. With impaired renal function, particularly with creatinine clearance < 35 ml/min, the elimination of bleomycin is delayed. **Contraindications:** Hypersensitivity to bleomycin; acute lung infection or severely reduced lung function; bleomycin-related lung toxicity or reduced lung function which can indicate bleomycin-related lung toxicity; ataxia telangiectasia; breast-feeding. **Undesirable effects:** Like most cytostatic drugs bleomycin can cause both an acute and a delayed toxic effect. Acute symptoms: anorexia, fatigue, nausea, fever. *Infections, infestations:* Infection, Sepsis (frequency not known). *Blood, lymphatic system:* Uncommonly bone marrow suppression, leukopenia, neutropenia, thrombocytopenia, haemorrhage. Rarely febrile neutropenia. Pancytopenia, anaemia (frequency not known). *Immune system:* Commonly hypersensitivity, idiosyncratic reaction, anaphylactic reaction. Anaphylactic reactions may be immediate or delayed for several hours, and usually occur after the first or second dose. It consists of hypotension, mental confusion, fever, chills, wheezing and can be fatal. *Metabolism, nutrition*: Very commonly decreased appetite. *Nervous system:* Paraesthesia, hyperaesthesia (frequency not known). *Cardiac:* Rarely myocardial infarction, coronary artery disease. *Vascular:* Rarely vascular injury, cerebral blood flow disorders, cerebral vasculitis, Haemolytic uraemic syndrome, arterial thrombosis. Hypotension, deep vein thrombosis, Raynaud's phenomenon (frequency not known). *Respiratory, thoracic, mediastinal:* Very commonly interstitial pneumonia, pulmonary fibrosis. Commonly acute respiratory distress syndrome, pulmonary embolism. Risk of pulmonary toxicity increases with the cumulative doses. Pulmonary toxicity can already occur with very low cumulative doses in elderly patients, patients who have received radiation of the thorax or who are receiving oxygen. Vascular changes occur in the lung, which partially affect the elasticity of the vessel wall. If unexplained coughing, dyspnoea, basal crepitations or a diffuse reticular image occurs on the X-ray of the thorax, any of these symptoms is a reason to discontinue the administration of bleomycin until the bleomycin toxicity has been ruled out as a cause. *Gastrointestinal:* Very commonly nausea, vomiting, mucosal inflammation, stomatitis, mucosal ulceration. Uncommonly diarrhoea. *Hepatobiliary:* Rarely hepatic impairment. *Skin, subcutaneous tissue:* Very commonly flagellate dermatitis, hyperpigmentation, skin hypertrophy, hyperkeratosis, erythema, rash, skin striae, blister, nail disorder, alopecia. Scleroderma (frequency not known). *Musculoskeletal, connective tissue:* Myalgia, pain in extremity, scleroderma (frequency not known). *Reproductive system:* Spermatozoa abnormal (frequency not known). *General, administration site:* Very commonly local swelling (fingertips and pressure susceptible places). Commonly pyrexia. Rarely hypotension, hyperpyrexia after intra-cavity administration. Very rarely tumour lysis syndrome. Injection site pain, infusion site thrombophlebitis (frequency not known). *Investigations:* Very commonly weight decreased. **Legal classification**: POM (prescription only medicine). **Marketing authorisation holder:** medac GmbH, Theaterstraße 6, 22880 Wedel, Germany. **Date of revision of text**: 03/2023
Bleomedac / Bleomycin medac has been authorised in Czech Republic, Estonia, Germany, Latvia, Lithuania, The Netherlands, Poland, Slovak Republic, Slovenia