Temomedac 5mg, 20mg, 100mg, 140mg, 180mg, 250mg hard capsules
Qualitative and quantitative composition: Each hard capsule contains 5mg (20mg; 100mg; 140mg; 180mg; 250mg) temozolomide. Excipients: Each hard capsule contains 87mg (72mg; 84mg; 117mg; 150mg; 209mg) of anhydrous lactose. Sodium starch glycolate Type A, colloidal anhydrous silica, tartaric acid, stearic acid, gelatine, titanium dioxide (E171), shellac, propylene glycol. 5mg, 100mg additionally: Yellow iron oxide (E172). 5mg, 140mg additionally: Indigo carmine (E132) aluminium lake 20mg additionally: Sunset yellow FCF aluminium lake (E110). 100mg, 180mg additionally: Red iron oxide (E172). 250mg additionally: Black iron oxide (E172). **Therapeutic indications:** Treatment of adult patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment. Treatment of children from the age of three years, adolescents and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy. **Posology and method of administration:** Newly diagnosed glioblastoma multiforme: In the concomitant phase, TMZ is administered orally at a dose of 75 mg/m² daily for 42 days concomitant with focal radiotherapy (60 Gy administered in 30 fractions). Delay or discontinuation of TMZ administration should be decided weekly according to toxicity criteria. Four weeks after completing the TMZ + RT, TMZ is administered for up to 6 cycles of monotherapy treatment. Dose in Cycle 1 is 150 mg/m² once daily for 5 days followed by 23 days without treatment. At Cycle 2, the dose is escalated to 200 mg/m² if possible. Recurrent or progressive malignant glioma: A treatment cycle comprises 28 days. In patients previously untreated with chemotherapy, TMZ is administered orally at a dose of 200 mg/m² once daily for the first 5 days followed by a 23 day treatment interruption (total of 28 days). In patients previously treated with chemotherapy, the initial dose is 150 mg/m² once daily, to be increased in the second cycle to 200 mg/m² if there is no haematological toxicity. Temomedac hard capsules should be administered in the fasting state. They must be swallowed whole with a glass of water and must not be opened or chewed. If vomiting occurs after the dose is administered, a second dose should not be administered that day. **Contraindications:** Hypersensitivity to temozolomide, any of the excipients or dacarbazine; severe myelosuppression. **Undesirable effects:** Type and frequency depend on whether TMZ is used in combination with RT or as monotherapy and whether for newly-diagnosed or recurrent disease. *Infections, infestations:* Commonly infections, herpes zoster, pharyngitisa, candidiasis oral. Uncommonly opportunistic infection (including PCP); sepsis, meningoencephalitis herpetic, hepatitis B virus including cases with fatal outcome; CMV infection, CMV reactivation, herpes simplex, infection reactivation, wound infection, gastroenteritis. *Neoplasm:* Uncommonly myelodysplastic syndrome (MDS), secondary malignancies, including myeloid leukaemia. *Blood, lymphatic system:* Commonly febrile neutropenia, neutropenia, thrombocytopenia, lymphopenia, leukopenia, anaemia. Uncommonly prolonged pancytopenia, aplastic anaemia including cases with fatal outcome, pancytopenia, petechiae. *Immune system:* Commonly allergic reaction. Uncommonly anaphylaxis. *Endocrine:* Commonly cushingoid. Uncommonly diabetes insipidus. *Metabolism, nutrition:* Very commonly anorexia. Commonly hyperglycaemia. Uncommonly hypokalemia, alkaline phosphatase increased. *Psychiatric:* Commonly agitation, amnesia, depression, anxiety, confusion, insomnia. Uncommonly behaviour disorder, emotional lability, hallucination, apathy. *Nervous system:* Very commonly convulsions, hemiparesis, aphasia/dysphasia, headache. Commonly ataxia, balance impaired, cognition impaired, concentration impaired, consciousness decreased, dizziness, hypoesthesia, memory impaired, neurologic disorder, neuropathy, paraesthesia, somnolence, speech disorder, taste perversion, tremor. Uncommonly status epilepticus, hemiplegia, extrapyramidal disorder, parosmia, gait abnormality, hyperaesthesia, sensory disturbance, coordination abnormal. *Eye:* Commonly hemianopia, vision blurred, vision disorder, visual field defect, diplopia, eye pain. Uncommonly visual acuity reduced, eyes dry. *Ear, labyrinth:* Commonly deafness, vertigo, tinnitus, earache. Uncommonly hearing impairment, hyperacusis, otitis media. *Cardiac:* Uncommonly palpitation. *Vascular:* Commonly haemorrhage, embolism pulmonary, deep vein thrombosis, hypertension. Uncommonly cerebral haemorrhage, flushing, hot flushes. *Respiratory, thoracic, mediastinal:* Commonly pneumonia, dyspnoea, sinusitis, bronchitis, coughing, upper respiratory infection. Uncommonly respiratory failure including cases with fatal outcome, interstitial pneumonitis/pneumonitis, pulmonary fibrosis, nasal congestion. *Gastrointestinal:* Very commonly diarrhoea, constipation, nausea, vomiting. Commonly stomatitis, abdominal pain, dyspepsia, dysphagia. Uncommonly abdominal distension, faecal incontinence, gastrointestinal disorder, haemorrhoids, mouth dry. *Hepatobiliary:* Uncommonly hepatic failure including cases with fatal outcome, hepatic injury, hepatitis, cholestasis, hyperbilirubinemia. *Skin, subcutaneous tissue:* Very commonly rash, alopecia. Commonly erythema, dry skin, pruritus. Uncommonly toxic epidermal necrolysis, Stevens-Johnson syndrome, angioedema, erythema multiforme, erythroderma, skin exfoliation, photosensitivity reaction, urticaria, exanthema, dermatitis, sweating increased, pigmentation abnormal. Frequency not known: Drug reaction with eosinophilia and systemic symptoms (DRESS). *Musculoskeletal, connective tissue:* Commonly myopathy, muscle weakness, arthralgia, back pain, musculoskeletal pain, myalgia. *Renal, urinary:* Commonly micturition frequency, urinary incontinence. Uncommonly dysuria. *Reproductive system:* Uncommonly vaginal haemorrhage, menorrhagia, amenorrhoea, vaginitis, breast pain, impotence. *General, administration:* Very commonly fatigue. Commonly fever, influenza-like symptoms, asthenia, malaise, pain, oedema, oedema peripheral. Uncommonly condition aggravated, rigors, face oedema, tongue discolouration, thirst, tooth disorder. *Investigations:* Commonly liver enzymes elevation, weight decreased, weight increased. Uncommonly Gamma-glutamyltransferase increased. *Injury:* Commonly radiation injury. **Legal classification**: POM (prescription only medicine). **Marketing authorisation number:** EU/1/09/605/001-012 **Marketing authorisation holder:** medac GmbH, Theaterstraße 6; 22880 Wedel, Germany. **Date of revision of text**: 03/2022
Temomedac has been authorised in all countries of the EU as well as in Iceland, Norway, Liechtenstein, Ukraine