Metotab® 2.5 mg / 7.5 mg/ 10 mg tablets
Qualitative and quantitative composition: One tablet contains 2.5 (7.5; 10) mg methotrexate (as methotrexate disodium). Excipients: Lactose monohydrate, pregelatinised starch, magnesium stearate. **Therapeutic indications:** Severe, active rheumatoid arthritis in adult patients. Severe and generalised psoriasis vulgaris, especially plaque-type, in adult patients which does not respond to conventional therapy. **Posology and method of administration:** Metotab is for oral use. The tablet should be swallowed whole with water. The recommended initial dose is 7.5 mg of methotrexate once weekly. Depending on the individual activity of the disease and tolerability by the patient, the initial dose may be increased gradually by 2.5 mg per week. A weekly dose of 25 mg should not be exceeded. **Important warning:** In the treatment of rheumatoid arthritis and psoriasis vulgaris, Metotab must only be taken once a week. Dosage errors in the use of Metotab can result in serious adverse reactions, including death. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients; severe liver impairment; alcohol abuse; severe renal impairment (creatinine clearance less than 30 ml/min.); pre-existing blood dyscrasias, such as bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anaemia; serious, acute or chronic infections such as tuberculosis, HIV or other immunodeficiency syndromes; ulcers of the oral cavity and known active gastrointestinal ulcer disease; pregnancy, breast-feeding; concurrent vaccination with live vaccines. **Undesirable effects:** *Infections, infestations:* Uncommonly pharyngitis. Rarely infection (incl. reactivation of inactive chronic infection), sepsis, conjunctivitis. *Neoplasms:* Very rarely lymphoma. *Blood, lymphatic system:* Commonly leukopenia, anaemia, thrombopenia. Uncommonly pancytopenia. Very rarely agranolocytosis, severe courses of bone marrow depression, lymphoproliferative disorders. Eosinophilia (frequency not known). *Immune system:* Rarely allergic reactions, anaphylactic shock, hypogammaglobulinaemia. *Metabolism, nutrition:* Uncommonly precipitation of diabetes mellitus. *Psychiatric:* Uncommonly depression, confusion. Rarely mood alterations. *Nervous system:* Commonly headache, tiredness, drowsiness. Uncommonly dizziness, cognitive dysfunction. Very rarely pain, muscular asthenia or paraesthesia in the extremities, paraesthesia/hypoaesthesia, changes in sense of taste (metallic taste), convulsions, meningism, acute aseptic meningitis, paralysis. Encephalopathy/leukoencephalopathy (frequency not known). *Eye:* Rarely visual disturbances. Very rarely impaired vision, retinopathy. *Cardiac, vascular:* Rarely pericarditis, pericardial effusion, cardiac tamponade. *Vascular:* Rarely hypotension, thromboembolic events. *Respiratory, thoracic, mediastinal:* Commonly pneumonia, interstitial alveolitis/pneumonitis, often associated with eosinophilia. Symptoms indicating potentially severe lung injury (interstitial pneumonitis) are: dry, not productive cough, short of breath and fever. Rarely pulmonary fibrosis, Pneumocystis jirovecii-pneumonia, shortness of breath and bronchial asthma, pleural effusion. Epistaxis, pulmonary alveolar haemorrhage (frequency not known). *Gastrointestinal:* Very commonly stomatitis, dyspepsia, nausea, loss of appetite, abdominal pain. Commonly oral ulcers, diarrhoea. Uncommonly gastrointestinal ulcers and bleeding, enteritis, vomiting, pancreatitis. Rarely malabsorption, gingivitis. Very rarely hematemesis, hematorrhoea, toxic megacolon. *Hepatobiliary:* Very commonly abnormal liver function tests (increased ALAT, ASAT, alkaline phosphatase and bilirubin). Uncommonly cirrhosis, liver atrophy, fibrosis and fatty degeneration of the liver, decrease in serum albumin. Rarely acute hepatitis. Very rarely hepatic failure. *Skin, subcutaneous tissue:* Commonly exanthema, erythema, pruritus. Uncommonly photosensitivity reactions, loss of hair, increase in rheumatic nodules, skin ulcer, herpes zoster, vasculitis, herpetiform eruptions of the skin, urticaria. Rarely increased pigmentation, petechiae, acne, ecchymosis, allergic vasculitis. Very rarely Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), increased pigmentary changes of the nails, acute paronychia, furunculosis, telangiectasias. Drug reaction with eosinophilia and systemic symptoms [DRESS], dermatitis, skin exfoliation/dermatitis exfoliative (frequency not known). *Musculoskeletal:* Uncommonly arthralgia, myalgia, osteoporosis. Rarely stress fracture. Osteonecrosis of jaw secondary to lymphoproliferative disorders (frequency not known). *Renal, urinary:* Uncommonly inflammation and ulceration of the urinary bladder, renal impairment, disturbed micturition. Rarely renal failure. oliguria, anuria, electrolyte disturbances. Proteinuria (frequency not known). *Reproductive system:* Uncommonly inflammation and ulceration of the vagina. Very rarely loss of libido, impotence, gynaecomastia, oligospermia, impaired oogenesis, impaired spermatogenesis, sterility, impaired menstruation, vaginal discharge. *General:* Rarely fever, wound-healing impairment. Asthenia, oedema (frequency not known). **Legal classification**: POM (prescription only medicine). **Marketing authorisation holder:** medac GmbH, Theaterstraße 6; 22880 Wedel, Germany. **Date of revision of text**: 28.08.2024
Metotab® has been authorised in Germany (metex® Tabletten), Sweden, Ukraine (not all strengths are authorized in all countries)