Capecitabine medac 150 mg /500 mg film-coated tablets
Qualitative and quantitative composition: Each film-coated tablet contains 150 mg (500 mg) capecitabine. *Excipients:* Each film-coated tablet contains 7 mg (25 mg) anhydrous lactose, cellulose, microcrystalline (E460), Croscarmellose sodium (E468), Hypromellose (E464), Magnesium stearate (E572), Talc, Titanium dioxide (E171), Iron oxide red, Iron oxide yellow (E172). **Therapeutic indications:** Adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer; metastatic colorectal cancer. First-line treatment of advanced gastric cancer in combination with a platinum based regimen. In combination with docetaxel treatment of locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy, previous therapy should have included an anthracycline. Monotherapy for locally advanced or metastatic breast cancer after failure of taxanes and an anthracycline containing chemotherapy regimen or for whom further anthracycline therapy is not indicated. **Posology and method of administration:** Dose depends on indication and schedule. Capecitabine medac tablets should be swallowed whole with water within 30 minutes after a meal and should not be crushed or cut. **Contraindications:** History of severe and unexpected reactions to fluoropyrimidine therapy; hypersensitivity to the active substance, excipients or fluorouracil; known complete dihydropyrimidine dehydrogenase (DPD) deficiency; pregnancy and lactation; severe leukopenia, neutropenia, or thrombocytopenia; severe hepatic impairment or renal impairment (creatinine clearance below 30 ml/min); recent or concomitant treatment with brivudine. If contraindications exist to any of the medicinal products in the combination regimen, that medicinal product should not be used. **Undesirable effects:** *Infections, infestations:* Herpes viral infection (zoster, oral), nasopharyngitis, lower or upper respiratory tract infection, rhinitis, sepsis, urinary tract infection, cellulitis, tonsillitis, pharyngitis, oral candidiasis, influenza, gastroenteritis, fungal infection, infection, tooth abscess. *Neoplasm:* Lipoma. *Blood, lymphatic system:* Neutropenia, anaemia, neutropenis fever, bone marrow depression, febrile neutropenia, pancytopenia, granulocytopenia, thrombocytopenia, leukopenia, haemolytic anaemia, INR increased/Prothrombin time prolonged. *Immune system:* Hypersensitivity. angioedema. *Metabolism, nutrition:* Anorexia, dehydration, weight decreased, diabetes, hypokalaemia, hyponatraemia, hypomagnesaemia, hypocalcaemia, hyperglycaemia, appetite disorder, malnutrition, hypertriglyceridaemia. *Psychiatric:* Insomnia, sleep disorder, depression, confusional state, panic attack, anxiety, depressed mood, libido decreased. *Nervous system:* Headache, lethargy, dizziness, paraesthesia, dysaesthesia, dysgeusia, aphasia, memory impairment, ataxia, syncope, balance disorder, sensory disorder, peripheral (sensory) neuropathy, neurotoxicity, tremor, neuralgia, hypersensitivity reaction, hypoaesthesia, toxic leukoencephalopathy. *Eye:* Lacrimation increased, conjunctivitis, eye irritation, visual acuity reduced, diplopia, lacrimal duct stenosis, corneal disorders, keratitis, punctate keratitis, visual disorders, dry eye, eye pain, visual impairment, vision blurred. *Ear, labyrinth:* Vertigo, ear pain, tinnitus, hypoacusis. *Cardiac:* Angina unstable, angina pectoris, myocardial ischaemia, atrial fibrillation, arrhythmia, tachycardia, sinus tachycardia, palpitations, ventricular fibrillation, QT prolongation, torsade de pointes, bradycardia, vasospasm. *Vascular:* Thrombophlebitis, deep vein thrombosis, hypertension, petechiae, hypotension, hot flush, peripheral coldness, lower limb oedema, embolism and thrombosis, flushing, hypertensive crisis, phlebitis. *Respiratory, thoracic, mediastinal:* Dyspnoea, epistaxis, cough, rhinorrhoea, pulmonary embolism, pneumothorax, haemoptysis, asthma, dyspnoea exertional, sore throat, dysaesthesia pharynx, hiccups, pharyngolaryngeal pain, dysphonia. *Gastrointestinal:* Diarrhoea, vomiting, nausea, stomatitis, abdominal pain, (upper) gastrointestinal or rectal haemorrhage, constipation, upper abdominal pain, dyspepsia, flatulence, dry mouth, mouth ulceration, oral pain, intestinal obstruction, ascites, enteritis, gastritis, dysphagia, abdominal pain lower, oesophagitis, abdominal discomfort, gastrooesophageal reflux disease, colitis, blood in stool, abdominal pain lower, oral dysaesthesia, paraesthesia oral, hypoaesthesia oral. *Liver:* Hyperbilirubinaemia, liver function test abnormalities, jaundice, hepatic failure, cholestatic hepatitis. *Skin, subcutaneous tissue:* Palmar-plantar erythrodysaesthesia syndrome, rash (erythematous), alopecia, erythema, dry skin, pruritus, skin hyperpigmentation, rash macular, skin desquamation, dermatitis, pigmentation disorder, nail disorder, blister, skin ulcer, urticaria, photosensitivity reaction, palmar erythema, swelling face, purpura, radiation recall syndrome, cutaneous lupus erythematosus, severe skin reactions such as Stevens-Johnson Syndrome and toxic Epidermal Necrolysis, hyperhidrosis, night sweats. *Musculoskeletal, connective tissue:* Pain in extremity or jaw, back pain, myalgia, arthralgia, joint swelling, bone pain, facial pain, musculoskeletal stiffness, muscular weakness, trismus, muscle spasm. *Renal, urinary:* Hydronephrosis, urinary incontinence, haematuria, proteinuria, creatinine renal clearance decreased, dysuria, nocturia, blood creatinine increased, acute renal failure secondary to dehydration. *Reproductive system:* Vaginal haemorrhage. *General:* Fatigue, asthenia, pyrexia, oedema peripheral, malaise, chest pain, oedema, chills, influenza-like illness, rigors, body temperature increased, weakness, lethargy, temperature intolerance, mucosal inflammation, pain in limb, pain, chills, chest pain, influenza-like illness, fever, infusion-related reaction, injection site reaction, infusion site pain, injection site pain. Contusion. In the instance of exposure to crushed or cut capecitabine tablets, eye irritation, eye swelling, skin rash, headache, paresthesia, diarrhea, nausea, gastric irritation, and vomiting have been reported. **Legal classification**: POM (prescription only medicine). **Marketing authorisation number:** EU/1/12/802/001-014; EU/1/12/802/029-042. **Marketing authorisation holder:** medac GmbH, Theaterstraße 6; 22880 Wedel, Germany. **Date of revision of text**: 02/2025
Capecitabine medac has been authorised in all countries of the EU as well as in Iceland, Norway