Irinotecan (Hydrochloride) medac 20 mg/mL, concentrate for solution for infusion
Qualitative and quantitative composition: 1 mL of the concentrate for solution for infusion contains 20 mg irinotecan hydrochloride trihydrate, equivalent to 17.33 mg irinotecan. Each vial of 2 mL (5 mL; 15 mL; 25 mL; 50 mL) contains 40 mg (100 mg; 300 mg; 500 mg; 1000 mg) of irinotecan hydrochloride trihydrate. *Excipients:* Sorbitol 45mg/mL, lactic acid, sodium hydroxide, water for injections. **Therapeutic indications:** Treatment of patients with advanced colorectal cancer: In combination with 5-FU and folinic acid in patients without prior chemotherapy for advanced disease; as single agent in patients who have failed an established 5-FU containing treatment regimen. In combination with cetuximab for the treatment of patients with EGFR-expressing, KRAS wild-type metastatic colorectal cancer without prior treatment for metastatic disease or after failure of irinotecan-including cytotoxic therapy. In combination with 5-FU, folinic acid and bevacizumab for first-line treatment of patients with metastatic carcinoma of the colon or rectum. In combination with capecitabine with or without bevacizumab for first-line treatment of patients with metastatic colorectal carcinoma. **Posology and method of administration:** For adults only. After dilution the irinotecan solution for infusion should be infused into a peripheral or central vein. *Recommended dosage:* In monotherapy for previously treated patients 350 mg/m² as an intravenous infusion over a 30- to 90-minute period every 3 weeks. Irinotecan plus 5-FU/FA: In every-2-weeks schedule 180 mg/m² of irinotecan once every 2 weeks as an intravenous infusion over a 30- to 90-minute period, followed by infusion with folinic acid and 5-FU. In the weekly schedule, the administration of irinotecan at 80 mg/m² is followed by infusion with folinic acid and then by 5-FU over 6 weeks. For other combinations and dosage adaptions refer to SPC. *Impaired renal function:* not recommended. *Elderly:* Dose should be chosen carefully. **Contraindications:** Chronic inflammatory bowel disease and/or bowel obstruction; hypersensitivity to active substance or to any of the excipients; breast-feeding; bilirubin > 3 times the ULN; severe bone marrow failure; WHO performance status > 2; concomitant use with St.John's wort; live attenuated vaccines. For additional contraindications of cetuximab, bevacizumab or capecitabine, refer to the product information for these products. **Undesirable effects:** *Infections, infestations:* Commonly infection. Frequency not known: Pseudomembranous colitis one of which has been documented bacteriologically (Clostridium difficile), sepsis, fungal infections (e.g. pneumocystis jirovecii pneumonia, bronchopulmonary aspergillosis, systemic candida), viral infections (e.g. herpes zoster, influenza, hepatitis B reactivation, cytomegalovirus colitis). *Blood and lymphatic system:* Very commonly neutropenia, anaemia, thrombocytopenia. Commonly febrile neutropenia. Frequency not known: Thrombocytopenia with antiplatelet antibodies. *Immune system:* Frequency not known: Hypersensitivity, anaphylactic reaction. *Metabolism, nutrition:* Very commonly decreased appetite. Frequency not known: Dehydration (due to diarrhoea and vomiting), hypovolaemia. *Nervous system:* Very commonly cholinergic syndrome. Frequency not known: Speech disorder generally transient in nature (in some cases, attributed to the cholinergic syndrome observed during or shortly after infusion of irinotecan), paraesthesia, muscular contractions involuntary. *Cardiac:* Frequency not known: Hypertension (during or after infusion), cardio circulatory failure (in patients who experienced episodes of dehydration associated with diarrhoea and/or vomiting, or sepsis). *Vascular:* Frequency not known: Hypotension (in patients who experienced episodes of dehydration associated with diarrhoea and/or vomiting, or sepsis). *Respiratory, thoracic and mediastinal:* Uncommonly interstitial lung disease presenting as lung infiltration, early effects such as dyspnoea. Frequency not known: Dyspnoea, hiccups. *Gastrointestinal:* Very commonly diarrhoea, vomiting, nausea, abdominal pain. Commonly constipation. Frequency not known: Intestinal obstruction, ileus (cases of ileus without preceding colitis have also been reported), megacolon, gastrointestinal haemorrhage, colitis (in some cases complicated by ulceration, bleeding, ileus, or infection), typhlitis, colitis ischaemic, colitis ulcerative, symptomatic or asymptomatic pancreatic enzymes increase, intestinal perforation. *Hepatobiliary:* Frequency not known: Steatohepatitis, hepatic steatosis. *Skin, subcutaneous tissue:* Very commonly reversible alopecia. Frequency not known: Skin reaction. *Musculoskeletal, connective tissue:* Frequency not known: Cramps. *Renal, urinary:* Frequency not known: Renal impairment, acute renal failure generally in patients who become infected and/or volume depleted from severe gastrointestinal toxicities, renal insufficiency (in patients who experienced episodes of dehydration associated with diarrhoea and/or vomiting, or sepsis). *General, administration site:* Very commonly mucosal inflammation, pyrexia, asthenia. Frequency not known: Infusion site reaction. *Investigations:* Very commonly transaminases (ALT and AST) increased, blood bilirubin increased, blood alkaline phosphatase increased. Commonly blood creatinine increased. Very rarely transaminases increased (i.e. AST and ALT) in the absence of progressive liver metastasis. Frequency not known: Amylase increased, lipase increased, hypokalaemia, hyponatraemia mostly related with diarrhoea and vomiting. **Legal classification**: POM (prescription only medicine). **Marketing authorisation holder:** medac GmbH, Theaterstraße 6; 22880 Wedel, Germany. **Date of revision of text**: 10/2022
Irinotecan medac has been authorised in France, Germany, Pakistan, United Kingdom