Mitomycin medac 20 mg, Powder and solvent for intravesical solution
Qualitative and quantitative composition: Each vial of Mitomycin medac contains 20 mg mitomycin. *Excipient:* Urea. Solvent for intravesical solution: Sodium chloride and water for injections.
Mitomycin medac, 40 mg, Powder and solvent for intravesical solution
Qualitative and quantitative composition: Each vial of Mitomycin medac contains 40 mg mitomycin. *Excipient:* Urea. Solvent for intravesical solution: Sodium chloride and water for injections.
Mitomycin medac 1 mg/ml powder for solution for injection/infusion or intravesical use
Qualitative and quantitative composition: Each vial of Mitomycin medac contains 2 mg (10 mg / 20 mg / 40 mg) mitomycin. *Excipient:* Urea.
Therapeutic indications: Mitomycin medac is indicated as intravesical administration for relapse prevention in adults with superficial urinary bladder carcinoma after transurethral resection. *Mitomycin medac 1 mg/ml powder additionally:* Mitomycin is used in palliative tumour therapy. Intravenous use of mitomycin is indicated as monochemotherapy or in combined cytostatic chemotherapy in adults with advanced colorectal, gastric, oesophageal, cervical, pancreatic carcinoma, advanced and/or metastatic breast carcinoma; non-small-cell bronchial carcinoma; advanced tumours of the head and neck. **Posology and method of administration:** *For intravesical use following reconstitution:* Unless otherwise specified, the dose of mitomycin is 20-40 mg mitomycin instilled into the bladder once weekly. Regimens with instillations every 2 weeks, every month or 3 monthly can also be used. It is advised to use this medicinal product at its optimal pH (urinary pH > 6) and to maintain the concentration of mitomycin by reducing fluid intake before, during and after instillation. The bladder must be emptied before instillation with a catheter. Mitomycin is introduced into the bladder by means of a catheter and at low pressure. The length of individual instillation should be 1 – 2 hours. During this period the solution should have sufficient contact with the entire mucosal surface of the bladder. Therefore the patient should be mobilised as much as possible. After 2 hours the patient should void the instilled solution, preferably in a sitting position. *Intravenous administration:* It is essential that the injection is administered intravenously. If the medicinal product is injected perivasally, extensive necrosis occurs in the area concerned. In cytostatic monochemotherapy, mitomycin is usually administered intravenously as a bolus injection. The recommended doses are 10-20 mg/m^2 body surface area every 6-8 weeks, 8-12 mg/m^2 body surface area every 3-4 weeks or 5-10 mg/m^2 of body surface every 3-6 weeks, depending on the therapeutic scheme used. In combination therapy, the dose is considerably lower. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients, breastfeeding. *Intravesical therapy:* Bladder wall perforation, cystitis. *Intravenous therapy:* Pancytopenia, isolated leukopenia or thrombocytopenia, haemorrhagic diathesis and acute infections are absolute contraindications. Restrictive or obstructive disturbances to pulmonary ventilation, renal dysfunction, hepatic dysfunction and/or a poor general state of health are relative contraindications. Temporal connection with radiotherapy or other cytostatics may be a further contraindication. **Undesirable effects:** *Intravesical therapy: Skin, subcutaneous tissue:* Commonly pruritus, allergic skin rash, contact dermatitis, palmar-plantar erythema. Rarely generalised exanthema. *Renal, urinary:* Commonly cystitis (possibly haemorrhagic), dysuria, nocturia, pollakisuria, haematuria, local irritation of the bladder wall. Very rarely necrotising cystitis, allergic (eosinophilic) cystitis, stenosis of the efferent urinary tract, reduction in bladder capacity, bladder wall calcification and bladder wall fibrosis, bladder perforation. In case of extravasation: bladder perforation, (fat) tissue necrosis of the surrounding area, vesical fistula, abscesses (frequency not known). After intravesical administration, only minor amounts of mitomycin reach the systemic circulation. Nevertheless, in very rare cases the following systemic undesired effects have been reported: Leukocytopenia, thrombocytopenia; interstitial lung disease; nausea, vomiting, diarrhoea; transaminases increased; alopecia; renal dysfunction; fever. *Systemic therapy: Blood, lymphatic system:* Very commonly bone marrow suppression, leukopenia, thrombocytopenia. Rarely haemolytic anaemia, thrombotic microangiopathy (TMA), incl. thrombotic thrombocytopenic purpura (TTP). Anaemia (frequency not known). *Infections, infestations:* Rarely life-threatening infection, sepsis. Infection (frequency not known). *Immune system:* Very rarely severe allergic reaction. *Cardiac:* Rarely heart failure after previous therapy with anthracyclines. *Respiratory, thoracic and mediastinal:* Commonly interstitial pneumonia, dyspnoea, cough, shortness of breath. Rarely pulmonary hypertension, pulmonary veno-occlusive disease (PVOD). *Gastrointestinal:* Very commonly nausea, vomiting. Uncommonly mucositis, stomatitis, diarrhoea, anorexia. *Hepatobiliary:* Rarely liver dysfunction, increased transaminases, jaundice, veno-occlusive disease (VOD) of the liver. *Skin, subcutaneous tissue:* Commonly exanthema, allergic skin rash, contact dermatitis, palmar-plantar erythema. Uncommonly alopecia. Rarely generalised exanthema. *Renal, urinary:* Commonly renal dysfunction, increase in serum creatinine, glomerulopathy, nephrotoxicity. Rarely haemolytic uraemic syndrome (HUS) commonly fatal, microangiopathic-haemolytic anaemia (MAHA syndrome). *General, administration site:* Commonly cellulitis, tissue necrosis following extravasation. Uncommonly fever. **Legal classification**: POM (prescription only medicine).
Marketing authorisation holder: medac GmbH, Theaterstraße 6; 22880 Wedel, Germany. **Date of revision of text:** 04/2024
Mitomycin medac has been authorised in Austria, Czech Republic, Denmark, Estonia, Finland, Germany, Iceland, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Portugal, Slovak Republic, Sweden, United Kingdom (not all strengths are authorized in all countries)