Prescribing Information - Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Mitomycin medac (mitomycin), 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.
Therapeutic indications: Mitomycin medac is indicated as intravesical administration for relapse prevention in adults with superficial urinary bladder carcinoma after transurethral resection. **Posology and method of administration:** Unless otherwise specified, the dose of mitomycin is 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. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients, breastfeeding, bladder wall perforation and cystitis. **Undesirable effects:** *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. **See SmPC for details of other adverse events.**
Legal classification: POM (prescription only medicine).
Basic NHS Price: 40mg vial plus giving set: £135
Marketing authorisation holder: medac GmbH, Theaterstraße 6; 22880 Wedel, Germany.
Product information in the UK: medac Pharma, Scion House, Stirling University Innovation Park, Stirling FK9 4NF. T: 01786 458086. info@medacpharma.co.uk
Marketing authorisation number: PL 11587/0090
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to medac drug safety at: drugsafety@medac.de