



# PHYSION<sup>®</sup>

## PROTOCOLS

**SINGLE INTRAVESICAL INSTILLATION  
OF MITOMYCIN-C WITH EMDA  
IMMEDIATELY BEFORE TURBT  
FOR THE PROPHYLAXIS OF THE EARLY  
RECIDIVES OF VESICAL NEOPLASMS  
NON-INFILTRATING THE MUSCULAR TUNIC**

## ELIGIBILITY

- Patients with established endoscopic diagnosis of urothelial carcinoma of the bladder, primary and clinically non-infiltrating the muscular tunic
- Patients over the age of 18
- ECOG performance status between 0 and 2
- Hematology framework within the limits of the standard
- Renal function within the limits of the norm
- Liver function within the limits of the norm

## NEOADJUVANT TREATMENT

- Before the intravesical treatment the eligible patients must undergo:
  - renal and bladder ultrasound
  - cystoscopy
  - and/or urinary cytology on 3 samples taken for 3 consecutive days
- Mitomycin: dilute 40 mg of MMC C in 100 ml of sterile bidistilled water under a fume hood.
- Perform single MMC C instillation with EMDA 30/60 minutes before spinal or general anesthesia for endoscopic resection of bladder cancer.
- At the end of the treatment the mitomycin solution is evacuated by gravity through the catheter / electrode that is removed.



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- The patient is then subjected to anesthesia and endoscopic resection of bladder cancer.
- After the operation, a continuous bladder wash is applied for 8-18 hours to avoid clots or retention with related complications.
- Once the definitive histological diagnosis is obtained, the adjuvant treatment is established based on the pathological staging and the risk classification in accordance with the EAU guidelines.

## ADJUVANT TREATMENT

### LOW RISK PATIENT

No intravesical adjuvant treatment and follow-up with ultrasound, cystoscopy and urine cytology every 3 months for the first year.

### INTERMEDIATE RISK PATIENTS

Intravesical chemo-prophylaxis with EMDA / MMC: induction (6/8 weekly instillations x 6/8 consecutive weeks) and maintenance (3 monthly instillations, cycle to be repeated 2 times); follow-up: ultrasound, cystoscopy and urine cytology every 3 months for the first 2 years.

### HIGH RISK PATIENTS

Intravesical chemo-immuno-prophylaxis with BCG and EMDA / MMC: induction (9 weekly instillations: BCG + BCG + EMDA / MMC, cycle to be repeated 3 times) and maintenance (9 monthly instillations: EMDA / MMC + EMDA / MMC + BCG, cycle to be repeated 3 times) Follow-up: ultrasound, cystoscopy and urine cytology every 3 months for the next 2 years.



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## EXCLUSION CRITERIA

- Allergy and / or intolerance ascertained by the MMC
- Non-urothelial bladder carcinomas
- Previous diagnosis of malignant bladder tumors
- Previous intravesical treatments with immunotherapeutic and chemotherapeutic agents
- Previous or concomitant diagnosis of urothelial carcinomas of the high urinary tract and prostatic urethra
- Bladder capacity less than 200 ml
- Untreated concomitant urinary infections
- Severe systemic infections (sepsis)
- Concurrent treatments with immuno-suppressive agents
- Urethral malformations or stenoses that can prevent bladder catheterization and endoscopic procedures
- Other concomitant treatments: radiotherapy, systemic chemotherapy and therapies with biological response modifiers
- Pregnancy



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