

PHYSION[®]

INTRAVESICAL SEQUENTIAL ADMINISTRATION OF BCG AND EMDA-MYTOMICIN IN HIGH-RISK NMIBC

DRUG SOLUTION

Dilute 40 mg of mytomicin in:

- 100 ml bidistilled water if excipient is sodium chloride;
- 100 ml Sodium Chloride 0.9% if excipient is urea or mannitol

PARAMETERS

CATHETER-ELECTRODE	CE-DAS [®] UROGENICS [®] / S – Version PH00971301
CURRENT STRENGTH	23 mA / PULSED
TIME OF TREATMENT	20 min
POLARITY	POSITIVE (+)
RISE-RATE	40 μ A/sec

PROCEDURE

- . Start the protocol within 2-4 weeks after the endoscopic resection
- . Before the 1st instillation perform:
 - urine cytology on 3 samples
 - urine culture with antibiogram
 - blood count, renal and hepatic function test

INDUCTION

- . 3 triplets (BCG – BCG – EMDA MITO) repeated for 9 consecutive weeks
- . 1 instillation per week

1° Week: BCG

2° Week: BCG

3° Week: EMDA MITO

- Urine culture with antibiogram
- Blood count, renal and hepatic function test

4° Week: BCG

5° Week: BCG

6 ° Week: EMDA MITO

- Urine culture with antibiogram
- Blood count, renal and hepatic function test

7° Week: BCG

8° Week: BCG

9° Week: EMDA MITO

- Blood count, renal and hepatic function test
- Urine cytology on 3 samples (at 3-4 weeks from the last instillation)
- Urine culture (at 4 weeks from the last instillation)
- Cystoscopy (at 6 weeks from the last instillation)
- Renal and bladder ultrasound

MAINTENANCE

- . The maintenance can start immediately after the control cystoscopy
- . 1 instillation per month for 9 months: 3 cycles of EMDA MITO – EMDA MITO – BCG

1° MONTH: EMDA MITO

- Urine culture with antibiogram
- Blood count, renal and hepatic function test

2° MONTH: EMDA MITO

- Urine culture with antibiogram
- Blood count, renal and hepatic function test

3° MONTH: BCG

- Blood count, renal and hepatic function test
- Urine cytology on 3 samples (at 3-4 weeks from the last instillation)
- Urine culture (at 4 weeks from the last instillation)
- Cystoscopy (at 6 weeks from the last instillation)
- Renal and bladder ultrasound

4° MONTH: EMDA MITO

- Urine culture with antibiogram
- Blood count, renal and hepatic function test

5° MONTH: EMDA MITO

- Urine culture with antibiogram
- Blood count, renal and hepatic function test

6° MONTH: BCG

- Blood count, renal and hepatic function test
- Urine cytology on 3 samples (at 3-4 weeks from the last instillation)
- Urine culture (at 4 weeks from the last instillation)
- Cystoscopy (at 6 weeks from the last instillation)
- Renal and bladder ultrasound

7° MONTH: EMDA MITO

- Urine culture with antibiogram
- Blood count, renal and hepatic function test

8° MONTH: EMDA MITO

- Urine culture with antibiogram
- Blood count, renal and hepatic function test

9° MONTH: BCG

- Blood count, renal and hepatic function test
- Urine cytology on 3 samples (at 3-4 weeks from the last instillation)
- Urine culture (at 4 weeks from the last instillation)
- Cystoscopy (at 6 weeks from the last instillation)
- Renal and bladder ultrasound

CHECK EXAMS

- To be repeated **every 3 months** for the first 2 years:
 - URINE CYTOLOGY on 3 samples
 - CYSTOSCOPY/ECO
- To be repeated **every 6 months** from the 3rd to the 5th year:
 - URINE CYTOLOGY on 3 samples
 - CYSTOSCOPY/ECO
- To be repeated **every year** from the 6th to the 10th year:
 - URINE CYTOLOGY on 3 samples
 - CYSTOSCOPY/ECO
- To be repeated **every year** till the end of the follow-up
 - URO-CT