

BC Cancer Protocol Summary for Intravesical Therapy for Non-Muscle Invasive Bladder Cancer Using Gemcitabine

Protocol Code

GUBGEM

Tumour Group

Genitourinary

Contact Physician

Dr. Peter Black

ELIGIBILITY:

- Intermediate-risk non-muscle invasive bladder cancer
- BCG-ineligible or -intolerant high-risk non-muscle invasive bladder cancer
- BCG-unresponsive high-risk non-muscle invasive bladder cancer
- Post-transurethral bladder tumour resection (single peri-operative dose)

EXCLUSIONS:

- Known hypersensitivity reaction to gemcitabine
- Presence of gross hematuria
- Presence of untreated urinary tract infection
- Suspected bladder perforation

TESTS:

- No routine lab tests before each treatment

TREATMENT:

- Insert urinary catheter (insert foley)
- Empty bladder completely at time of catheterization

Intra-operative (single-dose):

Drug	Dose	BC Cancer Administration Guideline
gemcitabine	2000 mg	Intravesically diluted with normal saline up to 90 mL * Supply dose divided into two syringes Administer instillation into bladder via catheter (dwell time of 1-2 hours)

*This is a single dose given in operating room [or within 24 hours of transurethral bladder tumour resection.](#)

Induction:

Drug	Dose	BC Cancer Administration Guideline
gemcitabine	2000 mg	Intravesically diluted with normal saline up to 90 mL Supply dose divided into two syringes Administer instillation into bladder via catheter (dwell time of 1-2 hours)

- **Induction:** weekly for 6 doses
- After 1 to 2 hours unclamp the catheter and allow the urine and gemcitabine to drain into the drainage bag
- After one additional hour of diuresis, remove catheter

Maintenance:

Drug	Dose	BC Cancer Administration Guideline
gemcitabine	2000 mg	Intravesically diluted with normal saline up to 90 mL Supply dose divided into two syringes Administer instillation into bladder via catheter (dwell time of 1-2 hours)

- **Maintenance:** monthly for 10 doses, starting 6 weeks after end of induction (i.e. at 3 months)
- After 1 to 2 hours unclamp the catheter and allow the urine and gemcitabine to drain into the drainage bag
- After one additional hour of diuresis, remove catheter

PRECAUTIONS:

1. Patients should be advised to minimise oral fluids (especially those containing caffeine) for 6-8 hours before each treatment to minimise dilution of drug in the bladder.
2. Patient may experience some bladder irritation, with more frequent or painful urination, urination at night and some blood or tissue in the urine.
3. Cystoscopy will be performed by the urologist every three months during treatment (after induction and every third maintenance dose). **It is important not to delay cystoscopy appointments, since this leads to delays in booking and administration of intravesical therapy.**

Call Dr. Peter Black or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

Reference:

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2. Bartoletti R, Cai T, Gacci M, et al. Intravesical gemcitabine therapy for superficial transitional cell carcinoma: results of a phase II prospective multicenter study. *Urology* 2005;66:726-31.
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4. Kassouf W, Traboulsi S, Kulkarni G, et al. GUA guidelines on the management of non-muscle invasive bladder cancer. *Can Urol Assoc J* 2015;9(9-10):E690-E704.
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6. Messing E, Tangen C, Lerner S, et al. Effect of intravesical instillation of gemcitabine vs. saline immediately following resection of suspected low-grade non-muscle invasive bladder cancer on tumour recurrence. *JAMA* 2018;319:1880-8.
7. Skinner EC, Goldman B, Sakr WA, et al. SWOG S0353: Phase II trial of intravesical gemcitabine in patients with non muscle invasive bladder cancer and recurrence after 2 prior courses of intravesical bacillus Calmette-Guérin. *J Urol* 2013;190(4):1200-4.