

NON-FORMULARY**NAME OF DRUG**

BCG

CLASSIFICATION

Biologic Response Modifier

ALTERNATE NAMEBacillus Calmette-Guerin
ImmuCyst BCG Therapeutic,
oncoTICE

INDICATIONS

- treatment of carcinoma in situ of the urinary bladder
- local treatment of certain neoplasms such as malignant melanoma

PHARMACOLOGY

- attenuated bovine strain of Mycobacterium bovis which acts as a non-specific immune stimulant
- promotes a local inflammatory reaction with histiocytic and leukocytic infiltration in the urinary bladder. The local inflammatory reaction is associated with an apparent elimination or reduction of superficial cancerous lesions of the urinary bladder. The exact mechanism by which this occurs is unknown.
- the metabolic fate of BCG is unknown

RECONSTITUTION AND STABILITY

- refrigerate vials; stable at room temperature x 5 days
- To reconstitute: Use BCG Reconstitution Kit[®] distributed by Mayne Pharma (Canada). Using a 60mL syringe withdraw 50mL NS. Ensure stopcock is in the off position, remove the cap from the female Luer on the stopcock and attach the NS syringe to the female Luer. Remove the spike protector from the vial access device and push the vial securely into place. Reconstitute the drug by injecting 1 mL NS into the vial. Gently swirl the vial and withdraw the drug into the syringe, then back into the vial three times for a uniform mixture. Aspirate the reconstituted drug into the NS syringe. Remove the protective cap from the administration tube and attach the administration tube to the catheter. Turn the stopcock handle so that the off position points to the vial. Instill into the bladder.
- reconstituted solution stable x 2 hours in fridge
- do NOT expose to direct or indirect sunlight; exposure to artificial light should be kept to a minimum
- All BCG waste including bags, sets, tubing, catheters, gloves, etc. must be disposed of in the biohazard waste containers on the nursing unit.

COMPATIBILITY

- reconstituted solution is compatible with NS
- do NOT mix with other drugs

ROUTES OF ADMINISTRATION

- intravesical - 50mg in 50 mL NS instilled slowly by gravity; 2 hour retention time

VH & HSC ADMINISTRATION POLICY

NAME OF DRUG (cont)

BCG

ALTERNATE NAMEBacillus Calmette-Guerin,
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oncoTICE**DOSAGE**

- usual dose for bladder instillation; 50mg diluted in 50 mL NS and retained in the bladder for up to 2 hours; if used in combination with interferon, use 1/3 vial
- Induction: repeated once weekly for a total of 6 weeks
- Maintenance: repeated once weekly for 3 weeks every 6 months
- severe cystitis may require a 50% dose reduction

Note: oncoTICE 50 mg = Connaught ImmuCyst 81 mg

POTENTIAL HAZARDS OF PARENTERAL ADMINISTRATION

- significant cystitis for a few days is expected following intravesical administration (urinary frequency, dysuria, nocturia, hematuria)
- flu-like syndrome consists of fever, malaise, vomiting arthralgia, myalgia and headache. These symptoms respond to bed rest and antipyretic treatment.

IMPORTANT IMPLICATIONS

- for best results the patient's bladder should be emptied prior to instillation of BCG
- urine voided within 6 hours after instillation should be disinfected by adding 500 mL of undiluted bleach to the toilet bowl; allow to stand 15 minutes before flushing
- it is recommended that intravesical BCG not be administered any sooner than 1 to 2 weeks following bladder biopsy, transurethral resection or traumatic catheterization
- contraindicated in patients on immunosuppressive therapy or with compromised immune systems due to risk of overwhelming systemic Mycobacterium sepsis; patients with urinary tract infections due to the risks of disseminated BCG infection and greater severity of bladder irritation; patients with fever of unknown origin
- if systemic BCG infection is suspected, the patient should immediately be treated with fast-acting antituberculosis therapy
- with intravesical use, most local adverse reactions occur following the third intravesical instillation. Symptoms usually begin 2-4 hours after instillation and persist for 24-72 hours.