

Bacillus Calmette-Guerin (BCG) vaccine:

Class: Biological Response Modulator; Vaccine, Live (Bacterial)

Indications: -Immunization against tuberculosis
-Immunotherapy for bladder cancer

Available dosage form in the hospital: BCG for intravesical installation INJ

Trade Names: Tice BCG , ImmuCyst®; Oncotice™

Dosage:

- Immunization against tuberculosis:** Percutaneous: 0.2-0.3 mL (full strength dilution); conduct postvaccinal tuberculin test (5 TU of PPD) in 2-3 months; if test is negative, repeat vaccination. **Note:** Initial lesion usually appears after 10-14 days consisting of small, red papule at injection site and reaches maximum diameter of 3 mm in 4-6 weeks.
- Immunotherapy for bladder cancer:** Intravesicular: Note: Treatment should begin 7-14 days after biopsy or TUR. The contents of one vial is used for each dose.
 - TheraCys®: One dose instilled into bladder (retain for 2 hours) once weekly for 6 weeks followed by 1 treatment at 3, 6, 12, 18, and 24 months after initial treatment
 - TICE® BCG: One dose instilled into the bladder (retain for 2 hours) once weekly for 6 weeks (may repeat cycle 1 time) followed by approximately once monthly for at least 6-12 months.

Geriatric

Refer to adult dosing

Renal Impairment:

No dosage adjustment provided in manufacturer's labeling.

Hepatic Impairment:

No dosage adjustment provided in manufacturer's labeling.

Common side effect:

>10%:

Central nervous system: Malaise (7% to 40%), fever (17% to 38%), chills (9% to 34%), pain (17%)

Gastrointestinal: Nausea/vomiting (3% to 16%), anorexia/weight loss (2% to 11%)

Genitourinary: Dysuria (52% to 60%), bladder irritation (50%), urinary frequency (40% to 50%), hematuria (26% to 39%), cystitis (6% to 30%), urinary urgency (6% to 18%), urinary tract infection (2% to 18%)

Hematological: Anemia (<21%)

Miscellaneous: Flu-like syndrome (24% to 33%)

1% to 10%:

Central nervous system: Headache (2%)

Dermatologic: Rash (2% to 3%)

Gastrointestinal: Diarrhea (6%), abdominal pain (2% to 3%)

Genitourinary: Genital pain (10%), hemorrhagic cystitis (9%), bladder cramps/pain (6% to 8%), urinary incontinence (2% to 6%), contracted bladder (5%), nocturia (5%), urinary debris (2%), genital inflammation/abscess (2%)

Hematological: Leukopenia (<6%)

Neuromuscular & skeletal: Arthralgia/myalgia (3% to 7%), cramps/pain (4%), rigors (3%)

Renal: Renal toxicity (10%)

Respiratory: Pulmonary infection (<3%)

Miscellaneous: Infection (<1% to 5%), diaphoresis (3%), allergy (2%)

Pregnancy Risk Factor: C