

INLEXZO™ (gemcitabine intravesical system) Dosage and Administration

Gemcitabine intravesical system is an intravesical drug releasing system (iDRS), referred to as TAR-200 in literature

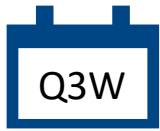
Gemcitabine intravesical system is indicated for the treatment of adult patients with BCG-unresponsive, NMIBC with CIS, with or without papillary tumors²



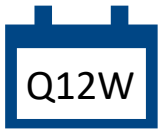
Gemcitabine intravesical system dosing schedule²

Administer **gemcitabine intravesical system*** intravesically only. Do NOT administer by any other route. Gemcitabine intravesical system is co-packaged with a urinary catheter and stylet used to insert gemcitabine intravesical system through the urinary catheter into the bladder. Administer using the co-packaged urinary catheter and stylet only.

Insertion schedule:^{†‡}



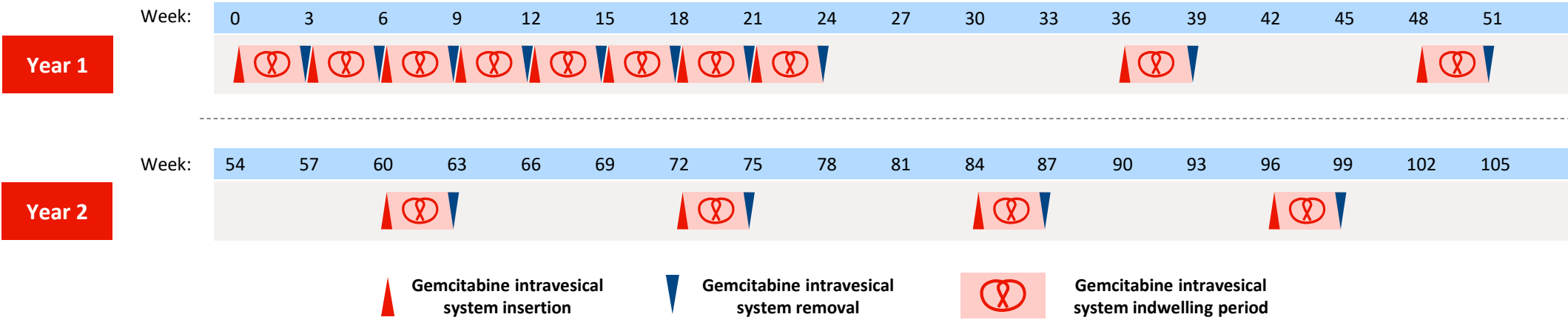
Up to 6 months
8 doses



Up to 18 months
6 doses

Removal schedule:

Remove gemcitabine intravesical system after each **3-week indwelling period**



*Contains 225 mg of gemcitabine. [†]Or until persistent or recurrent NMIBC, disease progression, or unacceptable toxicity. [‡]If a dose is missed, it should be administered as closely as possible to the original treatment schedule.

BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; iDRS, intravesical drug releasing system; NMIBC, non-muscle invasive bladder cancer; Q3W, once every 3 weeks; Q12W, once every 12 weeks.

1. Daneshmand S, et al. J Clin Oncol. 2025 Jul 30;101200/JCO2501651. doi: 10.1200/JCO-25-01651. 2. INLEXZO™ (gemcitabine intravesical system) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2025.