INLEXZO™ (gemcitabine intravesical system) Dosage and Administration

Gemcitabine intravesical system is an intravesical drug releasing system (iDRS), referred to as gem-iDRS and TAR-200 in literature[1]

Gemcitabine intravesical system is indicated for the treatment of adult patients with BCG-unresponsive, NMIBC with CIS, with or without papillary tumors[2]

Gemcitabine intravesical system recommended dosing schedule[2]

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.

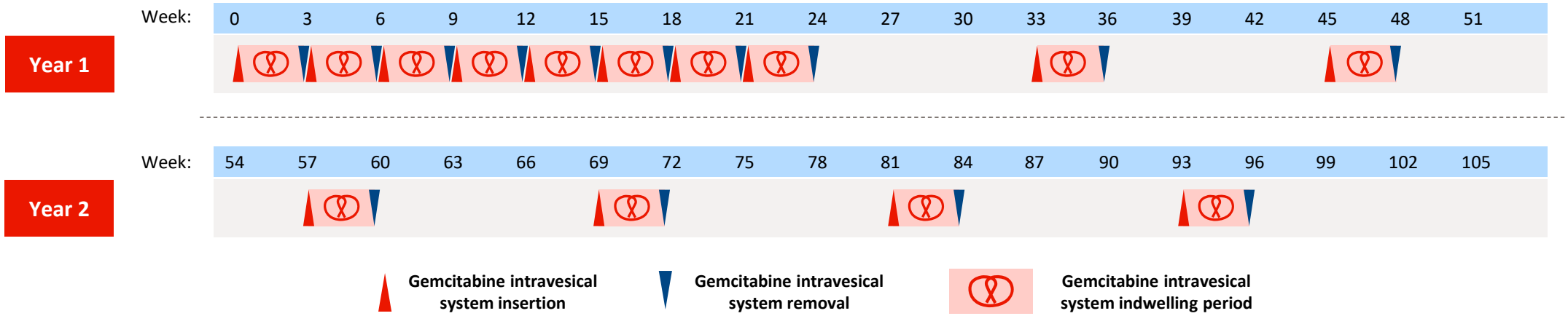
Insertion schedule:†‡

Q3W — Up to 6 months, 8 doses

Q12W — 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;43(33):3578–3588. 2. INLEXZO™ (gemcitabine intravesical system) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2025.

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INLEXZO™ (gemcitabine intravesical system) indication and safety information summary

Indication

INLEXZO™ (gemcitabine intravesical system) is indicated for the treatment of adult patients with Bacillus Calmette-Guerin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS), with or without papillary tumors.

Contraindications

INLEXZO™ is contraindicated in patients with:

- Perforation of the bladder
- Prior hypersensitivity reactions to gemcitabine or any component of the product.

Adverse Reactions

Serious adverse reactions occurred in 24% of patients receiving INLEXZO™. Serious adverse reactions that occurred in >2% of patients included urinary tract infection, hematuria, pneumonia, and urinary tract pain. Fatal adverse reactions occurred in 1.2% of patients who received INLEXZO™, including cognitive disorder.

The most common (>15%) adverse reactions, including laboratory abnormalities, were urinary frequency, urinary tract infection, dysuria, micturition urgency, decreased hemoglobin, increased lipase, urinary tract pain, decreased lymphocytes, hematuria, increased creatinine, increased potassium, increased AST, decreased sodium, bladder irritation, and increased ALT.

Warnings and Precautions

Risk in Patients with Perforated Bladder

INLEXZO™ may lead to systemic exposure to gemcitabine and to severe adverse reactions if administered to patients with a perforated bladder or to those in whom the integrity of the bladder mucosa has been compromised.

Evaluate the bladder before the intravesical administration of INLEXZO™ and do not administer to patients with a perforated bladder or mucosal compromise until bladder integrity has been restored.

Risk of Metastatic Bladder Cancer

Delaying cystectomy in patients with BCG-unresponsive CIS could lead to development of muscle invasive or metastatic bladder cancer, which can be lethal. The risk of developing muscle invasive or metastatic bladder cancer increases the longer cystectomy is delayed in the presence of persisting CIS.

Of the 83 evaluable patients with BCG-unresponsive CIS treated with INLEXZO™ in Cohort 2 of SunRISe-1, 7 patients (8%) progressed to muscle invasive (T2 or greater) bladder cancer. Three patients (3.5%) had progression determined at the time of cystectomy. The median time between determination of persistent or recurrent CIS or T1 and progression to muscle invasive disease was 94 days.

Magnetic Resonance Imaging (MRI) Safety

INLEXZO™ can only be safely scanned with MRI under certain conditions. Refer to section 5.3 of the USPI for details on conditions.

INLEXZO™ (gemcitabine intravesical system) indication and safety information summary (continued)

Warnings and Precautions (continued)

Embryo-Fetal Toxicity

Based on animal data and its mechanism of action, INLEXZO™ can cause fetal harm when administered to a pregnant woman if systemic exposure occurs. In animal reproduction studies, systemic administration of gemcitabine was teratogenic, embryotoxic, and fetotoxic in mice and rabbits.

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 6 months after final removal of INLEXZO™. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after final removal of INLEXZO™.

Use in Specific Populations

Pregnancy

There are no available data on the use of INLEXZO™ in pregnant women to inform a drug-associated risk. Please see Embryo-Fetal Toxicity for risk information related to pregnancy.

Lactation

Because of the potential for serious adverse reactions in breastfed infants, advise women not to breastfeed during treatment and for 1 week after final removal of INLEXZO™.

Females and Males of Reproductive Potential

Pregnancy Testing - Verify pregnancy status in females of reproductive potential prior to initiating INLEXZO™.

Contraception - Please see Embryo-Fetal Toxicity for information regarding contraception.

Infertility (Males) - Based on animal studies, INLEXZO™ may impair fertility in males of reproductive potential. It is not known whether these effects on fertility are reversible.

Geriatric Use

Of the patients given INLEXZO™ monotherapy in Cohort 2 of SunRISe-1, 72% were 65 years of age or older and 34% were 75 years or older. There were insufficient numbers of patients <65 years of age to determine if these patients respond differently to patients 65 years of age and older.

Scan QR code or click here to read the full Prescribing Information for INLEXZO™

Scan QR code or click here to read the Instruction for Use for INLEXZO™

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