inlexzo™
gemcitabine intravesical system | 225 mg

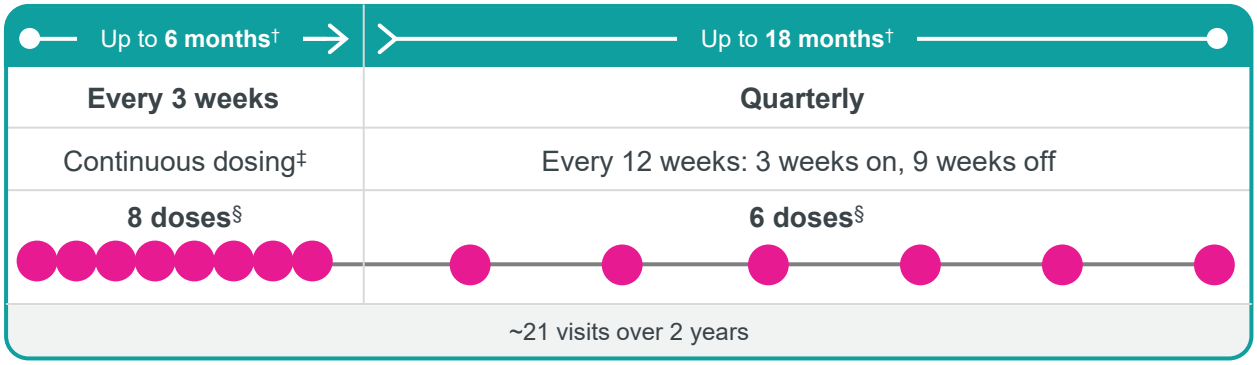
Dosing schedule

INDICATION

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

INLEXZO™ is administered in a familiar,* in-office procedure in 14 doses over 2 years[1]

Remove INLEXZO™ after each 3-week indwelling period[1]



*Uses catheterization and cystoscopy.[2] †Or until persistent or recurrent NMIBC, disease progression, or unacceptable toxicity.[1] ‡Assumes same-day removal and new insertion during first 6 months.[1] §One dose=insertion and removal 3 weeks later.[1]

Removal

- Removal by flexible or rigid cystoscope and non-cutting grasping forceps[2]
- Removal of INLEXZO™ by cystoscopy provides the opportunity for simultaneous assessment of disease response[1,3]

Missed Dose

- If a dose is missed, it should be administered as closely as possible to the original treatment schedule[1]

Prophylactic Antibiotics

- Prophylactic antibiotics may be used at the discretion of the treating healthcare provider with each INLEXZO™ insertion and removal[1]

MRI Scans

- INLEXZO™ may be used with MRI only under the specific pre-defined conditions provided below to avoid potential safety hazards or severe adverse reactions[1,2]
  - Static magnetic field of 1.5-Tesla and 3-Tesla, only
  - Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
  - Maximum magnetic resonance system reported, whole body averaged specific absorption rate of 2-W/kg for 60 minutes of continuous scanning in the Normal Operating Mode of operation for the MR system

Please read full Prescribing Information for specific MRI scanning conditions.

Please read full Instructions for Use for complete information on preparation, intravesical administration, and removal.

MRI=magnetic resonance imaging.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

INLEXZO™ (gemcitabine intravesical system) is contraindicated in patients with:

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

Please read additional Important Safety Information on page 2 and read full Prescribing Information and Instructions for Use for INLEXZO™.

See page 3 for important information and considerations for INLEXZO™.

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WARNINGS AND PRECAUTIONS

Risks 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 with Delayed Cystectomy

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.

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™.

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.

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.

Please read the full Prescribing Information and Instructions for Use for INLEXZO™.

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Important Information and Considerations

Administration Instructions[1]

- **Administer INLEXZO™ intravesically only. Do NOT administer by any other route. INLEXZO™ is co-packaged with a urinary catheter and stylet used to insert INLEXZO™ through the urinary catheter into the bladder. Administer using the co-packaged urinary catheter and stylet only**
- INLEXZO™ should be inserted and removed by a trained healthcare provider. Healthcare providers should become thoroughly familiar with the insertion and removal instructions before attempting insertion or removal of INLEXZO™

Handling Considerations[1]

- INLEXZO™ is a hazardous drug. Follow applicable special handling and disposal procedures while handling INLEXZO™ and during the insertion and removal procedure

Read full Instructions for Use for additional handling considerations.

Patient Counseling Regarding Intravesical Administration[1]

- Instruct patients to drink approximately 1500 mL/6-7 cups of fluid per day during therapy with INLEXZO™ to ensure adequate urine production for drug release
- Instruct patients not to empty the bladder immediately prior to the insertion procedure. Presence of urine in the bladder can facilitate deployment of INLEXZO™. Patients can resume micturition after the insertion procedure
- Advise patients to avoid contact with urine while INLEXZO™ is indwelling in the bladder for approximately 3 weeks and for at least 24 hours post-removal
- During indwelling period of approximately 3 weeks, advise patients to void urine sitting on a toilet, to wash hands with soap and water and to wash their genital area with water after each urination, and to flush the toilet after use
- Advise patients to wash clothing soiled with urine promptly and separately from other clothing
- Complete the MRI Safety Information Card and give it to the patient. Advise the patient to carry the card and show it to their HCP in case of need for MRI scans

Please refer to Section 17 of full Prescribing Information for complete patient counseling information.

Please read full Instructions for Use for complete information on preparation, intravesical administration, and removal.

IMPORTANT SAFETY INFORMATION (continued)

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References: 1. INLEXZO™ (gemcitabine intravesical system) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** INLEXZO™ (gemcitabine intravesical system) [Instructions for Use]. Horsham, PA: Janssen Biotech, Inc. **3.** American Cancer Society. Treatment of bladder cancer, based on the stage and other factors. Accessed September 8, 2025. https://www.cancer.org/cancer/types/bladder-cancer/treating/by-stage.html

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