Supplies and Equipment Needed for the Insertion and Removal of INLEXZO™ (gemcitabine intravesical system)

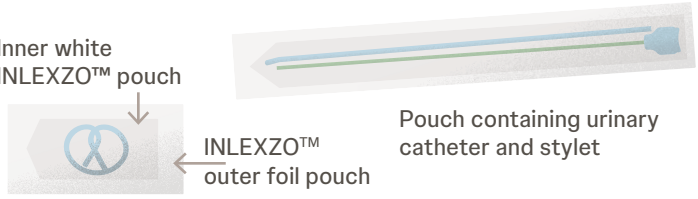
Scan the QR code or click **here** to read the **INLEXZO™ Instructions for Use** for complete information on preparation, intravesical administration, and removal of INLEXZO™

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

An INLEXZO™ carton contains: an INLEXZO™ pouch, an urinary catheter and stylet pouch, and an MRI Safety Information Card

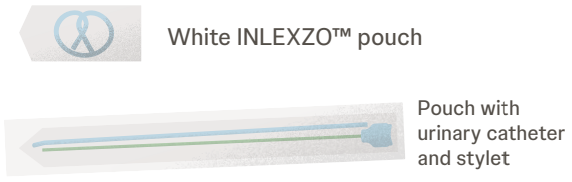
Preparing for insertion

Gather supplies



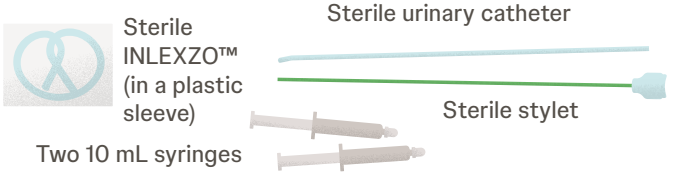
- ☐ INLEXZO™ silver outer foil pouch containing an inner white INLEXZO™ pouch
- ☐ Pouch containing urinary catheter and stylet
- ☐ Two 10 mL prefilled water-based lubricant syringes **OR** two empty 10 mL syringes and water-based lubricant
- ☐ Multiple pairs of gloves, including sterile gloves (see Instructions for Use)

Non-sterile work surface



Transfer to sterile work surface

Sterile work surface



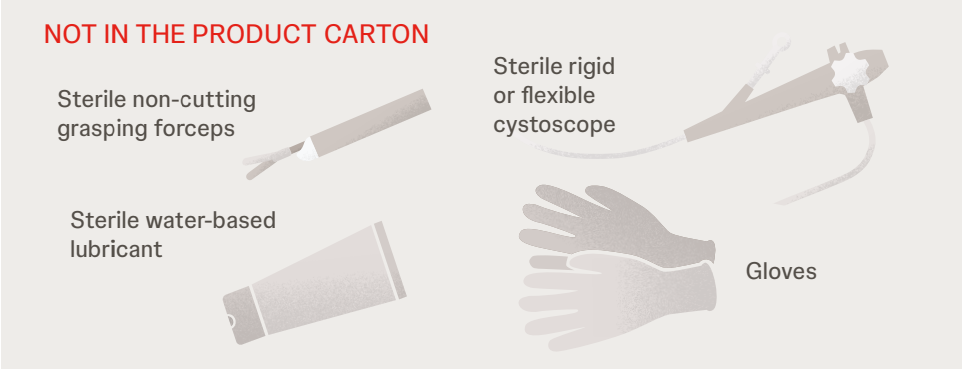
Preparing for removal

Gather supplies

- ☐ Non-cutting grasping forceps

⚠ Do not use cutting forceps

- ☐ Rigid or flexible cystoscope
- ☐ Water-based lubricant
- ☐ Pair of gloves



INLEXZO™ (gemcitabine intravesical system) [Instructions for Use]. Horsham, PA: Janssen Biotech, Inc. 2025.

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

Indication

INLEXZO™ 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.

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.

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.

ALT, alanine transaminase; AST, aspartate aminotransferase; BCG, Bacillus Calmette-Guerin; CIS, carcinoma *in situ*; MRI, magnetic resonance imaging; NMIBC, non–muscle-invasive bladder cancer; USPI, United States Prescribing Information; UTI, urinary tract infection.

INLEXZO™ [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

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PP/RD US-SFM-7617 05/26