Practical Tips for HCPs Supporting Patients Receiving Gem-iDRS

See Safety Information Summary on page 2

Gemcitabine intravesical system, referred to as gem-iDRS, was studied in adults with BCG-unresponsive NMIBC with CIS, with or without papillary tumors, in Cohort 2 of the SunRISe-1 study (safety population N=85).[1]

The most common ARs with gem-iDRS were:

- Urinary frequency
- Dysuria
- Urinary tract pain
- Bladder irritation
- UTI
- Micturition urgency
- Hematuria

Most ARs were Grade 1–2.[1,2] Median onset of ARs occurred within the first ~4 doses (median, 11.8 weeks; range, 0.1+ to 98.3 weeks). *ARs resolved† within ~3 weeks (median, 2.6 weeks; range, 0.1+ to 113.9+ weeks).[3]*

Patient education

Hydration and food considerations

- Instruct patients to drink approximately **1500 mL (6 to 7 cups) of fluids per day** during therapy with gem-iDRS to ensure adequate urine production for drug release[1]
- Consider advising patients to **avoid food** and **drinks that can make bladder symptoms worse**, such as **caffeine, alcohol, spicy foods,** and **drinks containing artificial sweeteners** (ie, carbonated drinks and flavored waters)[4,5]

Patient prophylaxis

- Bladder cancer and its treatments can increase the incidence of LUTS[2,4]
- In the **SunRISe-1 study**, investigators were instructed to[6]:
  - Administer **at least 1 dose of prophylactic periprocedural antibiotics** for any gem-iDRS insertion or removal
  - Consider **prophylactic administration of anticholinergics, NSAIDS, and bladder analgesics**

Urinary tract infection

Educate patients on mitigation strategies to help reduce the risk of UTIs such as:

- Using the restroom often and when needed[7]
- Wearing underwear made from cotton and loose-fitting pants[7]
- Taking showers instead of baths[8]

Urinary incontinence

- In patients who have concerns for incontinence, **consider incontinence management strategies** for patients who experience urinary urgency; protective products such as adult incontinence briefs/waterproof underwear, pads and external catheters can manage urine leaks[9]
- Consider advising patients to use **barrier creams** to **reduce skin irritation** associated with urinary incontinence[9]
- To avoid contact-related reactions, **during the indwelling period of approximately 3 weeks, advise patients to**[1]:
  - Avoid urine contact with skin during the indwelling period and for at least 24 hours post-removal
  - Void urine sitting on a toilet
  - Flush the toilet after each use
  - Wash hands with soap and water and wash genital area with water after each urination
  - Wash clothing soiled with urine promptly and separately from other clothing

Sexual activity and intimacy

- Participants in SunRISe-1 were required to follow contraceptive measures throughout the study and for 6 months after the final dose. Male participants were required to **use a condom during sexual activity**, and female participants of childbearing potential were required to use a **highly effective‡ method of contraception** (eg, IUD, implant, hormonal contraception, or sterilization)[6]
- The gem-iDRS prescribing information does not list any restrictions related to close-contact or intimacy between partners, including oral sex[1]

Dosage and administration

- Gem-iDRS should be inserted and removed by a trained HCP[1]
- Instruct patients not to empty the bladder immediately prior to the insertion procedure. Presence of urine in the bladder can facilitate deployment of gem-iDRS. Patients can resume micturition after the insertion procedure[6]
- Gem-iDRS must be removed after each 3-week indwelling period[1]

See the **Prescribing Information** and **Instructions for Use** for complete information on preparation, intravesical administration, and removal of gem-iDRS

Gem-iDRS is a hazardous drug. Follow applicable special handling and disposal procedures while handling gem-iDRS and during the insertion and removal procedure. Gemcitabine and the inactive uracil metabolite dFdU are excreted in the urine throughout the indwelling period. Of the total gemcitabine dose, 77% is excreted by Day 7, and 99% by Day 21[1]

*This was an analysis of ARs occurring in >15% of patients.[6] †Majority of ARs resolved: 88% (373/423). Duration of ARs was defined as the time from onset of ARs to resolution of event or clinical cutoff date if event was ongoing.[6] ‡Highly effective was defined as failure rate of <1% per year when used consistently and correctly.[10]

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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-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS), with or without papillary tumors. Prior hypersensitivity reactions to gemcitabine or any component of the product.

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

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

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™.

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™

AR, adverse reaction; BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; dFdU, days to first deterioration in urinary symptoms; gem-iDRS, gemcitabine intravesical system; HCP, healthcare provider; IUD, intrauterine device; LUTS, lower urinary tract symptoms; NMIBC, non-muscle–invasive bladder cancer; NSAID, non-steroidal anti-inflammatory drug;UTI, urinary tract infection.

1. INLEXZO™ [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2. Pradere B, et al. *Curr Opin Urol.* 2026;36(1):123-133. 3. Data on File. Johnson & Johnson. 2026. 4. National Cancer Institute. Urination Changes During Cancer Treatment. National Institutes of Health; 2022. Available at: https://www.cancer.gov/about-cancer/treatment/side-effects/urination-changes (Accessed June 17, 2026). 5. National Institute of Diabetes and Digestive and Kidney Diseases. Prevention of Bladder Control Problems (Urinary Incontinence) & Bladder Health. National Institutes of Health; 2021. Available at: https://www.niddk.nih.gov/health-information/urologic-diseases/bladder-control-problems/prevention (Accessed June 17, 2026). 6. Janssen Research & Development. SunRISe-1 Protocol 17000139BLC2001, Version 5; 2 July 2024. 7. National Institute on Aging. Bladder Health and Incontinence: Tips for Keeping Your Bladder Healthy. National Institutes of Health; 2023. Available at: https://www.nia.nih.gov/health/bladder-health-and-incontinence/15-tips-keep-your-bladder-healthy (Accessed June 17, 2026). 8. Centers for Disease Control and Prevention. Urinary Tract Infection Basics. Available at: https://www.cdc.gov/uti/about/index.html (Accessed June 17, 2026). 9. American Cancer Society. Bladder Incontinence (Urine Leakage). Available at: https://www.cancer.org/cancer/managing-cancer/side-effects/stool-or-urine-changes/bladder-incontinence.html (Accessed June 17, 2026).

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