inlexzo™
gemcitabine intravesical system | 225 mg

You are cordially invited to attend a live educational session

Introducing INLEXZO™: An Expert Panel Discussion on an Innovative New Drug Releasing System for Patients With BCG-UR NMIBC With CIS

This broadcast will present a 60-minute in-depth discussion on INLEXZO™ (gemcitabine intravesical system), focusing on its innovative design and the SunRISe-1 clinical study. Topics will include efficacy, safety information, and procedural education.

Dr. Gautam Jayram, MD
Urology Associates
Nashville, TN

Dr. Jeffrey Holzbeierlein, MD, FACS
The University of Kansas Cancer Center
Kansas City, KS

Dr. Suzanne Merrill, MD, FACS
United Urology Group
Lone Tree, CO

Speakers are paid consultants of Johnson & Johnson

Date

Wednesday, October 22, 2025
at 6:00 PM Pacific Time

Location

Le Papillon
410 Saratoga Avenue,
San Jose, California 95129
(408) 296-3730

We look forward to your participation in this informative discussion. Reserve your spot now by contacting your Johnson & Johnson Representative, Andrew Yonan at ayonan1@its.jnj.com (559) 471-6690, or visit https://janssenspeakerprograms.my.site.com/Registration/s?l=a12Vt000009WUdh

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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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

INLEXZO™ is contraindicated in patients with:

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

Please read the back page for additional Important Safety Information and accompanying full Prescribing Information and Instructions for Use for INLEXZO™.

Abbreviations: BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; NMIBC, non-muscle invasive bladder cancer; PhRMA, Pharmaceutical Research and Manufacturers of America; UR, unresponsive.

IMPORTANT SAFETY INFORMATION *(continued)*

WARNINGS AND PRECAUTIONS

Risks in Patients with Perforated Bladder

INLEXZO™ (gemcitabine intravesical system) 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 accompanying full Prescribing Information and Instructions for Use for INLEXZO™.

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