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Resource Pocket Guide

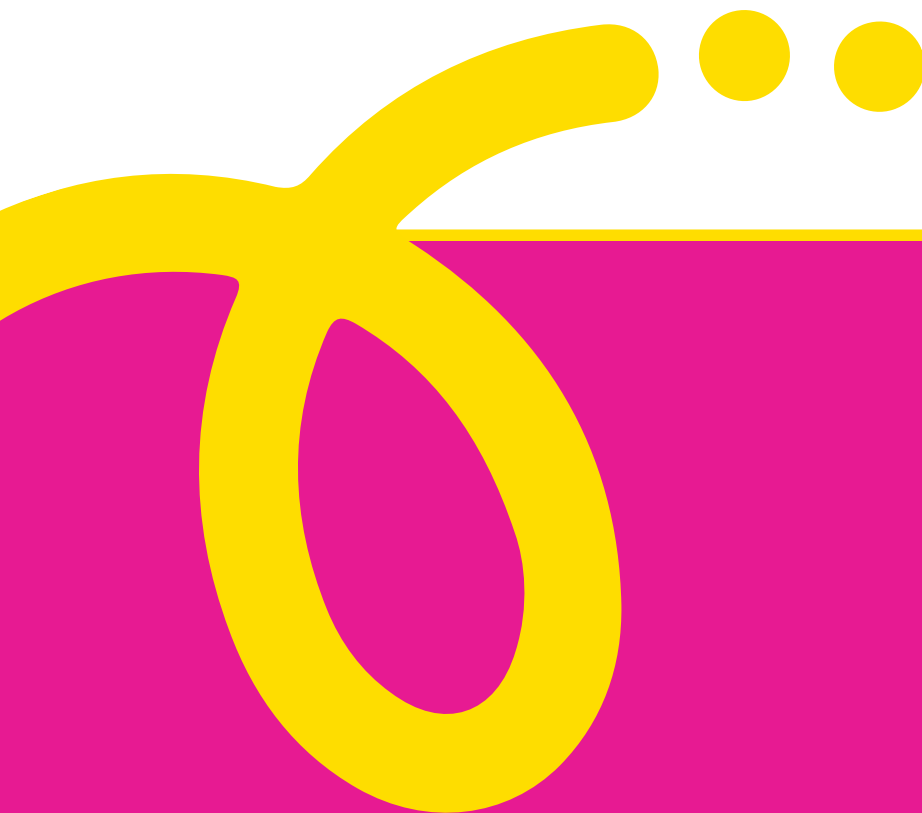




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INDICATION

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.

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.

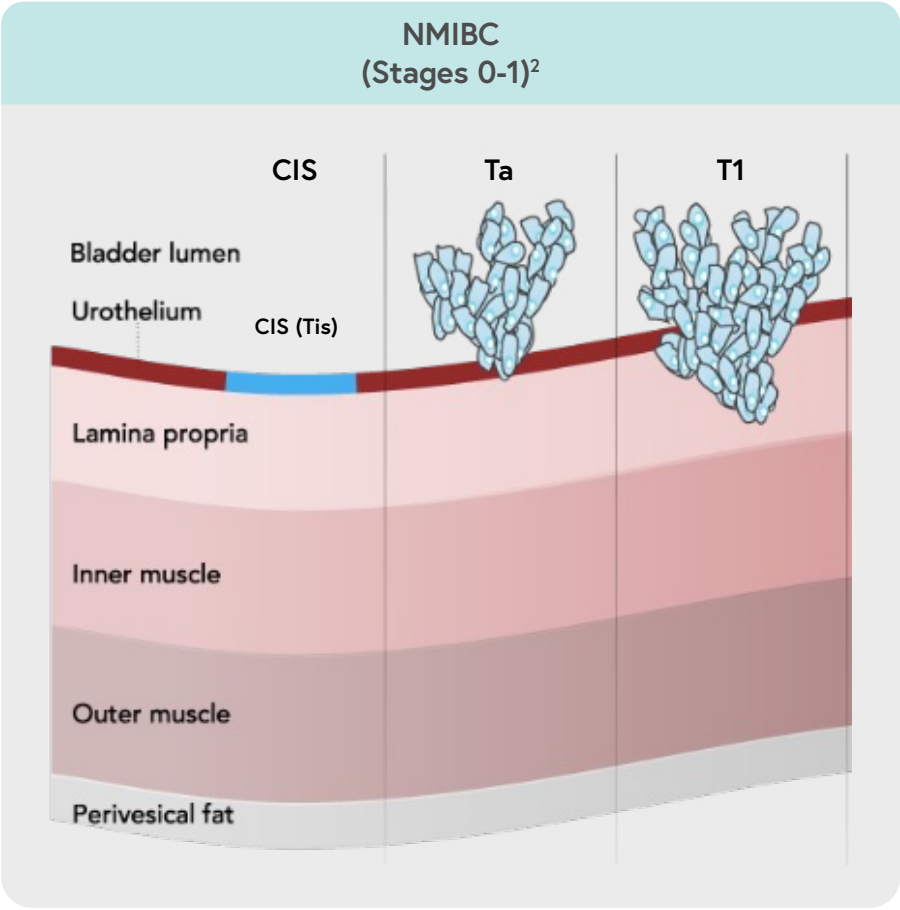
Staging and Risk Stratification

American Joint Committee on Cancer (AJCC) TNM System: NMIBC

The TNM system evaluates¹:

- T, the invasiveness of the primary tumor
- N, nearby lymph node involvement
- M, distant metastasis

See below for a visual representation of NMIBC*



- CIS, also known as Tis, is a flat, non-invasive carcinoma growing in the inner lining layer of the bladder only¹

Click on home icon to return to the Table of Contents page



Risk Stratification of NMIBC

- AUA risk stratification of NMIBC accounts for tumor size, invasiveness, grade, and other factors (Table 1)²

Table 1. AUA Risk Stratification for High-Risk NMIBC²

High Risk

High-grade T1

Any recurrent, high-grade Ta

High-grade Ta >3 cm (or multifocal)

Any CIS

Any BCG failure in high-grade case

Any variant histology

Any LVI

Any high-grade prostatic urethral involvement

AUA, American Urological Association; BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; LVI, lymphovascular invasion; NMIBC, non-muscle invasive bladder cancer; TNM, Tumor, Node, and Metastasis.

*The TNM classification system is not specific to NMIBC.¹

1. American College of Surgeons. American Joint Committee on Cancer Cancer Staging Systems. Accessed March 4, 2025.

<https://www.facs.org/quality-programs/cancer-programs/american-joint-committee-on-cancer/cancer-staging-systems/>
2. Holzbeierlein J, Bixler BR, Buckley DJ, et al. Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline: 2024 amendment. *J Urol*. 2024;10:1097/JU.0000000000003846

Innovation has arrived

INLEXZO™ is indicated for the treatment of adult patients with BCG-unresponsive, NMIBC with CIS, with or without papillary tumors¹

INLEXZO™ is the only FDA-approved intravesical drug releasing system^{1*}



*As of 09/25.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



About INLEXZO™

- INLEXZO™ is a sterile, non-resorbable intravesical system containing the equivalent of 225 mg gemcitabine (present as 256.3 mg of gemcitabine hydrochloride)¹



- INLEXZO™ contains an almost white to light pink-brown colored gemcitabine component at the center surrounded on each side by off-white to light-blue-colored osmotic components¹

How INLEXZO™ works

- INLEXZO™ provides prolonged delivery of gemcitabine into the bladder for weeks, not hours¹⁻³
- Of the total gemcitabine dose, 77% was excreted by Day 7 and 99% was excreted by Day 21 in urine as gemcitabine and dFdU¹
- INLEXZO™ is inserted via transurethral catheterization and removed via cystoscopy, both familiar, in-office procedures^{1,4}
- Once inserted, INLEXZO™ curls into a bi-oval shape—like a pretzel—designed to promote retention within the bladder^{1,5}
- INLEXZO™ remains freely mobile in the bladder throughout the indwelling period, even after voiding^{1,5}

BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; dFdU, 2'-deoxy-2',2'-difluorouridine; FDA, Food and Drug Administration; NMIBC, non-muscle invasive bladder cancer.

1. INLEXZO™ [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2. Data on File. Janssen Biotech, Inc.

3. Palugan L, et al. *Int J Pharm X*. 2021;3:100100. 4. INLEXZO™ [Instructions for Use]. Horsham, PA: Janssen Biotech, Inc.

5. Daneshmand S, et al. *Urol Oncol*. 2025;43(5):286-296.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Embryo-Fetal Toxicity (continued)

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™.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.





SunRISe-1 Trial Design¹

INLEXZO™ was evaluated in Cohort 2 of SunRISe-1, a single-arm, multi-center study of patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors

Population (N=83)

- BCG-unresponsive* NMIBC
- CIS, with or without papillary tumors
- Ineligible for or had elected to not undergo radical cystectomy



Every 3 weeks for up to 6 months, then once every 12 weeks for up to 18 months or until unacceptable toxicity, persistence or recurrence of CIS and/or high-grade papillary disease, or progression

Major Efficacy Outcome Measures

- CR rate at any time[†]
- Duration of response[‡]

- Mandatory biopsies were performed 24 and 48 weeks after treatment initiation
- Reinduction was not included in the study design[‡]

*BCG-unresponsive NMIBC CIS was defined as persistent or recurrent CIS alone or with Ta/T1 disease within 12 months of adequate BCG therapy. Adequate BCG therapy was defined as a minimum administration of at least 5 of 6 doses of an initial induction course plus either of: at least 2 of 3 doses of maintenance therapy or at least 2 of 6 doses of a second induction course.¹ [†]CR rate at any time was defined as negative results for cystoscopy (with TURBT/centrally reviewed biopsies as applicable) and centrally reviewed urine cytology.¹ [‡]DoR was defined from the time of first CR achieved to first evidence of recurrence, progression or death due to any cause (whichever was earlier) for participants who achieved a CR.³

IMPORTANT SAFETY INFORMATION 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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



Clinical Trial Results: SunRISe-1¹

Major Efficacy Outcome Measures

COMPLETE RESPONSE RATE*
82% (68/83)
(95% CI, 72-90)
CR was achieved without reinduction^{‡†}

DURABLE RESPONSE†
51% (35/68) of patients achieved a CR did not have a RC⁴
CR ≥12 months
(range: 0-44+ months)

Additional Data

- 92% (n=76/83) of evaluable patients did not progress to MIBC (≥T2)
- 8% (7/83) of evaluable patients experienced progression to MIBC (≥T2)
- 3.5% (3/83) had progression determined at cystectomy, with a median of 94 days between persistent/recurrent CIS or T1 and MIBC
- 84% (n=57/68) of patients who achieved a CR did not have a RC⁴
- Delaying cystectomy can lead to development of metastatic bladder cancer, which can be lethal.
- **Disclaimer:** This exploratory analysis is not in the Prescribing Information. It is being provided for descriptive purposes; results require cautious interpretation, as RC may have occurred after patient discontinuation
- Median follow-up time in responders: 20.2 months (range: 5-48 months)

BCG, Bacillus Calmette-Guérin; CI, confidence interval; CIS, carcinoma *in situ*; CR, complete response; DoR, duration of response; MIBC, muscle-invasive bladder cancer; NMIBC, non-muscle invasive bladder cancer; RC, radical cystectomy; TURBT, transurethral resection of bladder tumor.

*CR rate at any time was defined as negative results for cystoscopy (with TURBT/centrally reviewed biopsies as applicable) and centrally reviewed urine cytology.¹ [†]Based on patients (n=68) that achieved a CR at any time. DoR was defined from the time of first CR achieved to first evidence of recurrence, progression, or death due to any cause (whichever was earlier) for participants who achieved a CR.³ [‡]Reinduction was not included in the study design.²

1. INLEXZO™ [Prescribing Information]. Horsham, PA; Janssen Biotech, Inc. 2. Jacob JM, et al. Presented at: 120th American Urological Association Annual Meeting; April 26-29, 2025; Las Vegas, Nevada. 3. Janssen Research & Development, LLC. Phase 2b Clinical Study Evaluating Efficacy and Safety of TAR-200 in Combination with Cetrelimab, TAR-200 Alone, or Cetrelimab Alone in Participants with High-Risk Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Intravesical Bacillus Calmette-Guérin (BCG) who are Ineligible for or Elected Not to Undergo Radical Cystectomy. October 4, 2024. Accessed September 11, 2025. https://ascopubs.org/doi/suppl/10.1200/JCO-25-01651/suppl_file/protocol1_JCO-25-01651.pdf 4. Data on File. Janssen Biotech, Inc.

IMPORTANT SAFETY INFORMATION ADVERSE REACTIONS (continued)

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



Efficacy and Safety (continued)

Clinical Trial Results: SunRISe-1¹

Safety Profile

Table 1. Most Common ARs Occurring in >15% of Patients

Adverse reaction	INLEXZO™ (N=85)*	
	All Grades, %	Grades 3 or 4, %
Urinary frequency	48	0
Urinary tract infection	44	6
Dysuria	42	0
Micturition urgency	34	0
Urinary tract pain	26	7
Hematuria	24	2.4
Bladder irritation	16	0

Other clinically significant ARs (<15%) included fatigue (14%), genital pain (12%), diarrhea (11%), urinary incontinence (9%), urinary retention (7%), and nocturia (4.7%).

Table 2. Select Laboratory Abnormalities (>15%) that Worsened From Baseline

Laboratory Abnormality	INLEXZO™†	
	All Grades, %	Grades 3 or 4, %
Hematology		
Decreased hemoglobin	31	1.2
Decreased lymphocytes	24	4.8
Chemistry		
Increased lipase	28	12
Increased creatinine	24	0
Increased potassium	22	1.2
Increased AST	17	1.2
Decreased sodium	16	4.8
Increased ALT	16	1.2

ALT, alanine aminotransferase; AR, adverse reaction; AST, aspartate aminotransferase.

*The safety of INLEXZO™ monotherapy was evaluated in Cohort 2 of SunRISe-1, a multi-center, open-label study in 85 adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors.¹ †The denominator used to calculate the rate varied from 82 to 83 based on the number of patients with a baseline value and at least one posttreatment value.¹

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

IMPORTANT SAFETY INFORMATION 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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



Permanent Discontinuations

7% of patients permanently discontinued treatment due to ARs

- ARs which resulted in permanent treatment discontinuation (>1%) included bladder irritation, urinary frequency, cognitive disorder, hydronephrosis, and urinary tract disorder

Dosage Interruptions

41% of patients experienced dosage interruptions due to ARs

- ARs requiring dosage interruption in >3% of patients included urinary tract infection, urinary tract pain, hematuria, urinary frequency, micturition urgency, dysuria, and genital pain

AR, adverse reaction.

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

IMPORTANT SAFETY INFORMATION USE IN SPECIFIC POPULATIONS (continued)

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™.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.





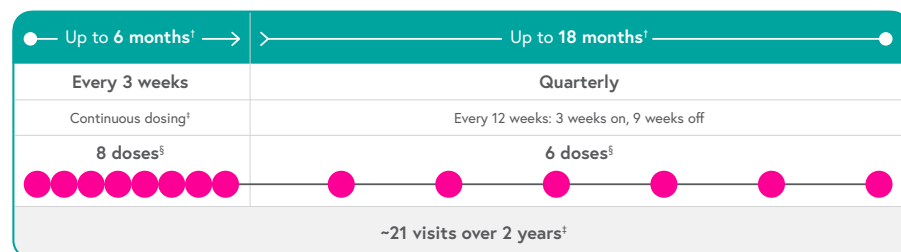
Dosing and Administration

Recommended Dosage and Administration

INLEXZO™ is administered in a familiar,* in-office procedure in 14 doses over 2 years¹



Remove INLEXZO™ after each 3-week indwelling period



*Uses catheterization and cystoscopy.² ¹Or until persistent or recurrent NMIBC, disease progression, or unacceptable toxicity.¹
¹Assumes same-day removal and new insertion during first 6 months.¹ ⁵One dose=insertion and removal 3 weeks later.¹

Removal

- Removal by flexible or rigid cystoscope and non-cutting grasping forceps²
- Removal of INLEXZO™ by cystoscopy provides the opportunity for simultaneous assessment of disease response³

Missed Dose

- If a dose is missed, it should be administered as closely as possible to the original treatment schedule¹

Prophylactic Antibiotics

- Prophylactic antibiotics may be used at the discretion of the treating healthcare provider with each INLEXZO™ insertion and removal¹

MRI Scans

- INLEXZO™ contains a metal wire. When INLEXZO™ is indwelling in the bladder, the patient can only be safely scanned with MRI under certain conditions^{1,2}
- Please read full [Prescribing Information](#) for INLEXZO™ for specific MRI scanning conditions

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS (continued)

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.

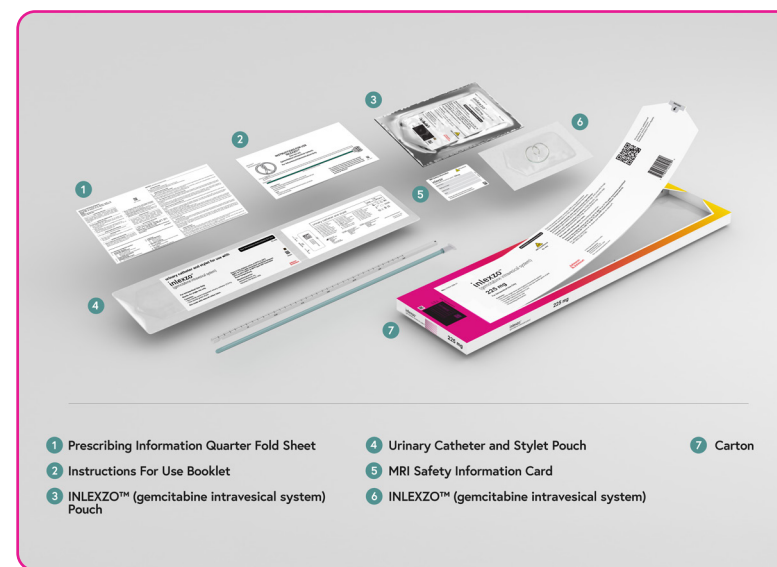
Infertility (Males) - Based on animal studies, INLEXZO™ may impair fertility in males of reproductive potential. It is not known whether these effects on fertility are reversible.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



Important Administration Instructions¹

- 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™



MRI, magnetic resonance imaging; NMIBC, non-muscle invasive bladder cancer.
1. INLEXZO™ [Prescribing Information]. Horsham, PA; Janssen Biotech, Inc. 2. INLEXZO™ [Instructions for Use]. Horsham, PA; Janssen Biotech, Inc. 3. Treatment of bladder cancer, based on the stage and other factors. American Cancer Society. Accessed May 7, 2025. <https://www.cancer.org/cancer/types/bladder-cancer/treating/by-stage.html>

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS (continued)

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 see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



Dosing and Administration (continued)

Handling Considerations¹

- 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 Administration¹

- 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. Instruct 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.

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.

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



Preparation, Insertion, and Removal



Scan here to learn more including a preparation, insertion and removal procedural video of the INLEXZO™ delivery system.

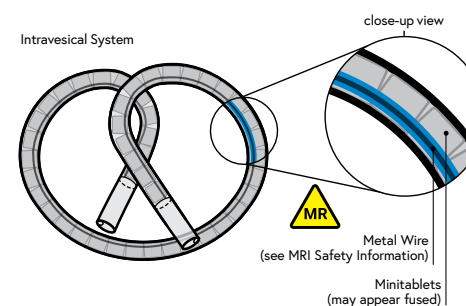


Data rates may apply.

Included in INLEXZO™ Carton²

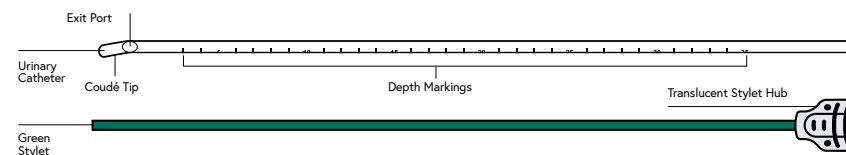
- One sterile INLEXZO™
 - INLEXZO™ contains minitables, which may appear fused (Figure 1)

Figure 1. INLEXZO™ Intravesical System



- One sterile urinary catheter and one sterile stylet (Figure 2)

Figure 2. Urinary Catheter and Stylet



MRI, magnetic resonance imaging.

1. INLEXZO™ [Prescribing Information]. Horsham, PA; Janssen Biotech, Inc. 2. INLEXZO™ [Instructions for Use]. Horsham, PA; Janssen Biotech, Inc.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



Preparation, Insertion, and Removal (continued)

Precautions

- INLEXZO™ is a hazardous drug. Follow applicable special handling and disposal procedures while handling INLEXZO™ and during the insertion and removal procedure. Dispose of the used urinary catheter and stylet, INLEXZO™, and its packaging per facility procedures and per applicable federal, state, and local regulations
- **Wear gloves, and take appropriate precautions, per local guidelines for handling hazardous drugs,** to prevent skin or mucus membrane exposure while handling INLEXZO™ and during the insertion and removal procedure
- If contact with INLEXZO™ is suspected, immediately wash the skin thoroughly or rinse the mucosa with copious amounts of water
- Advise patients and caregivers to **exercise caution when handling urine during indwelling period of approximately 3 weeks.** See INLEXZO™ [Prescribing Information](#) for details

Important Information

- **Use aseptic technique during insertion and removal of INLEXZO™**
 - Follow these instructions carefully to avoid patient injury and ensure proper functioning
- To ensure proper insertion of INLEXZO™ and to avoid damage to INLEXZO™, use only the following:
 - Water-based lubricant
 - Urinary catheter and stylet (supplied)
- **Do not** use the urinary catheter and stylet for any other purpose. Do not re-sterilize/re-use the urinary catheter or stylet. Re-use of the urinary catheter and stylet can lead to its degradation, failure, and contamination, which can increase the risk of infection or transmission of blood borne pathogens to patients and users
- **Do not** use any components that are damaged or have damaged packaging
- Check the expiration ('EXP') date before use
- **Do not** use INLEXZO™ if expiration date has passed
- To ensure proper INLEXZO™ removal and to avoid damage to INLEXZO™ and/or cystoscope, use only the following:
 - **Non-cutting,** grasping forceps
 - Flexible or rigid cystoscope
- Store in the original package at **20°C to 25°C (68°F to 77°F)**; with excursions permitted between **15°C to 30°C (59°F to 86°F)**

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Risk of Metastatic Bladder Cancer with Delayed Cystectomy (continued)

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



Prepare Components

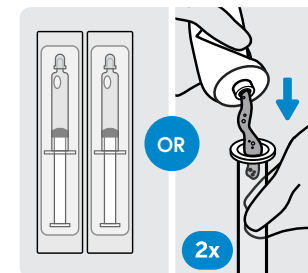
Step 1: Gather Supplies

- Included in product carton
 - One sterile INLEXZO™
 - One sterile urinary catheter and one sterile stylet
 - Not included in product carton
 - Multiple pairs of gloves
 - Two 10 mL prefilled water-based lubricant syringes
- OR
- Two empty 10 mL syringes and water-based lubricant

Step 2: Put on gloves

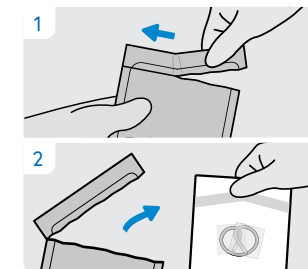
Step 3: Prepare two syringes with sterile water-based lubricant

- Remove each sterile syringe prefilled with **water-based** lubricant from its packaging and place each syringe on the sterile work surface using aseptic technique
- OR
- Fill each of the two empty syringes with 2 mL to 3 mL of **water-based** lubricant plus additional lubricant for urinary catheter tip lubrication
 - Place each lubricant syringe on a sterile work surface using aseptic technique
 - The lubricant is to be used to lubricate the tip of the urinary catheter and to facilitate the insertion of INLEXZO™



Step 4: Open the INLEXZO™ foil pouch

- Tear open the INLEXZO™ outer foil pouch at tear notch
- Remove the white INLEXZO™ inner pouch



1. INLEXZO™ [Instructions for Use]. Horsham, PA: Janssen Biotech, Inc.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.





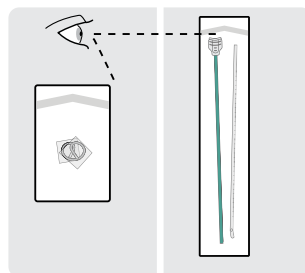
Prepare Components (continued)

Step 5: Examine the white component pouches for damage

- Check the white INLEXZO™ pouch and white pouch containing the urinary catheter and stylet for damage (e.g., cuts, tears, punctures) that could compromise sterility of the components before opening

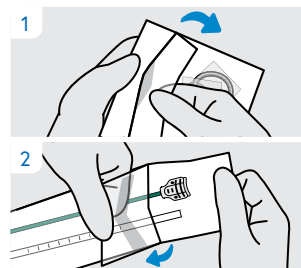
! Do not use if packaging is damaged.

! Surfaces of the white INLEXZO™ pouch and the white component pouches are not sterile.



Step 6: Open the white component pouches and transfer the contents onto a sterile work surface

- Open the white INLEXZO™ pouch and transfer INLEXZO™ onto a sterile work surface
- Do not remove plastic sleeves from INLEXZO™
- Open the white pouch containing the urinary catheter and stylet and transfer the contents onto a sterile work surface

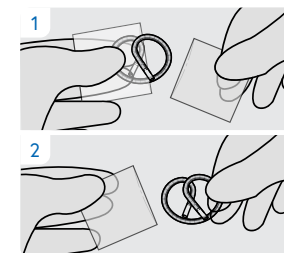


Step 7: Put on sterile gloves

- Ensure your patient is prepared for the procedure
- Put on sterile gloves

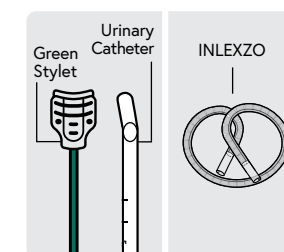
Step 8: Remove plastic sleeves

- Remove the plastic sleeves from INLEXZO™



Step 9: Inspect components

- Inspect INLEXZO™, the urinary catheter, and green stylet for damage
- **Do not use** if the urinary catheter or green stylet are damaged or if the outer surface of INLEXZO™ is damaged



INLEXZO™ [Instructions for Use]. Horsham, PA; Janssen Biotech, Inc..

IMPORTANT SAFETY INFORMATION

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™.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



IMPORTANT SAFETY INFORMATION

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.





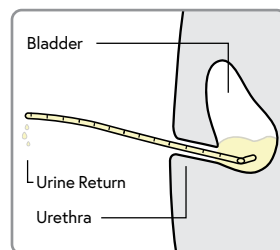
Insert INLEXZO™

Step 1: Lubricate the urinary catheter

- Lubricate tip of the urinary catheter
- The urinary catheter should be free of INLEXZO™ and the stylet

Step 2: Insert the urinary catheter (without stylet)

- Introduce the urinary catheter into the urethra by hand and advance until urine return. Do not empty the bladder
- Use depth markings to maintain coude tip orientation and insertion depth position throughout the procedure



! Do not excessively force the urinary catheter into the bladder.

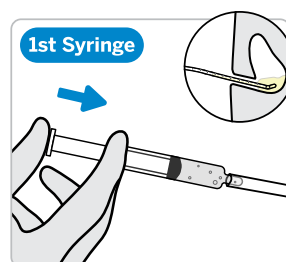
! In case of resistance, careful assessment and standard procedural techniques can be performed, as appropriate, in order to safely advance the urinary catheter into the bladder.

! If advancement is obstructed or cause cannot be determined or resolved, withdraw the urinary catheter to avoid patient injury or urinary catheter damage.

! Do not re-use urinary catheter.

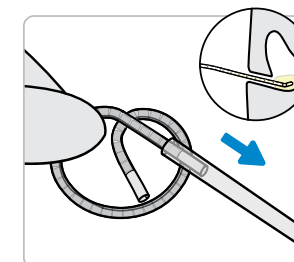
Step 3: Inject lubricant from the first syringe into the urinary catheter

- Inject 2 mL to 3 mL of lubricant from the first syringe into the end of the urinary catheter with the urinary catheter placed in the bladder



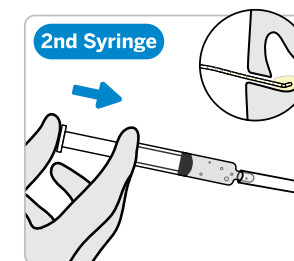
Step 4: Insert INLEXZO™ into the urinary catheter

- Insert either end of INLEXZO™ into the urinary catheter and advance until fully inserted



Step 5: Inject lubricant from the second syringe into the urinary catheter

- Inject 2 mL to 3 mL of lubricant from the second syringe into the urinary catheter to help advance INLEXZO™ further, with the urinary catheter placed in the bladder



INLEXZO™ [Instructions for Use]. Horsham, PA; Janssen Biotech, Inc.

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS (continued)

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 see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no available data on the use of INLEXZO™ in pregnant women to inform a drug-associated risk.

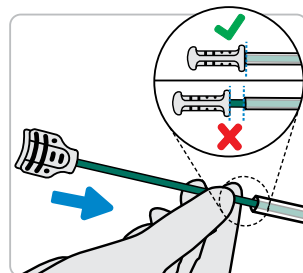
Please see Embryo-Fetal Toxicity for risk information related to pregnancy.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.

Insert INLEXZO™ (continued)

Step 6: Insert stylet into the urinary catheter

- Slowly insert stylet into the urinary catheter until the stylet hub is flush with end of the urinary catheter. This ensures INLEXZO™ exits the urinary catheter and enters the bladder



! If INLEXZO™ cannot be advanced, remove the urinary catheter and stylet together as a single unit

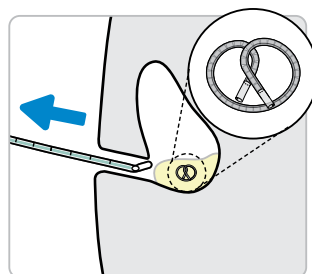
Ensure INLEXZO™ is also removed

Do not attempt to re-use the removed INLEXZO™

Begin again by obtaining a new carton of INLEXZO™ including a new urinary catheter and stylet

Step 7: Remove the urinary catheter and stylet together as a single unit

- Do not remove the urinary catheter and stylet individually
- INLEXZO™ should remain inside the bladder
- Retain Instructions for Use for the removal procedure



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.

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.

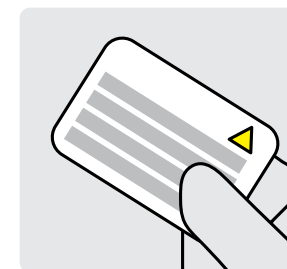
Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



Post-Insertion Instructions

Step 1: Provide the completed MRI Safety Information Card to the patient

- Remove the MRI Safety Information Card from the carton
- Complete the details and give it to the patient
- Advise the patient to carry the card and to show their current and future healthcare providers in case of need for MRI scans
 - INLEXZO™ contains a metal wire. The patient can safely undergo an MR exam only under very specific conditions (see MRI Safety Information)



Step 2: Inform the patient and caregivers about the indwelling period

- The indwelling period is approximately 3 weeks. See INLEXZO™ [Prescribing Information](#) for additional information
- Inform the patient and caregivers that INLEXZO™ will remain in the bladder for the indwelling dosing period
- INLEXZO™ contains a hazardous drug. The patient and caregivers should be made aware of the need to **exercise caution when handling urine during the indwelling period**. See INLEXZO™ [Prescribing Information](#) for additional information

MR, magnetic resonance; MRI, magnetic resonance imaging.
INLEXZO™ [Instructions for Use]. Horsham, PA; Janssen Biotech, Inc.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.

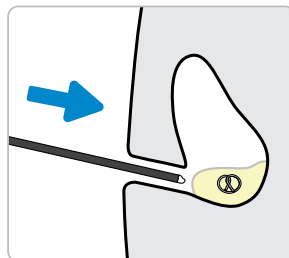




Removal of INLEXZO™ After the Indwelling Period

Step 1: Lubricate the cystoscope

- Use a water-based lubricant to lubricate the cystoscope

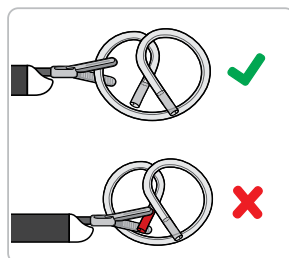


Step 2: Insert the cystoscope

- Insert cystoscope into the bladder to locate INLEXZO™

Step 3: Grasp INLEXZO™

- Introduce **non-cutting** grasping forceps through the working channel of the cystoscope



! Do not use cutting forceps

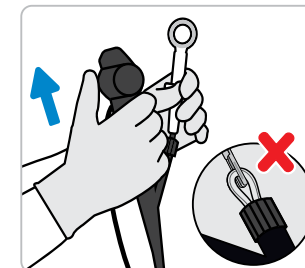
- Grasp INLEXZO™ over tubing and metal wire

! Do not grasp on or near the ends of INLEXZO™

- Grasping near the ends of INLEXZO™ could result in exposing the metal wire, potentially causing damage to surrounding tissue

Step 4: Remove INLEXZO™

- Remove the cystoscope and forceps out of the urethra **together** to remove INLEXZO™ under direct vision
- **Do not** remove INLEXZO™ through working channel of the cystoscope. Doing so may damage INLEXZO™ and/or the cystoscope



Step 5: Inspect INLEXZO™

! After removal, inspect INLEXZO™ to confirm it is intact and unbroken

Step 6: Product Disposal

- Dispose of the used urinary catheter and stylet, INLEXZO™, and its packaging per facility procedures and per applicable federal, state, and local regulations

INLEXZO™ [Instructions for Use]. Horsham, PA; Janssen Biotech, Inc.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



IMPORTANT SAFETY INFORMATION

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™.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



Storage, Handling, and Patient Counseling



Storage

- Store in the original carton at 20°C to 25°C (68°F to 77°F); with excursions permitted between 15°C to 30°C (59°F to 86°F).



Handling and Disposal

- INLEXZO™ is a hazardous drug. Follow applicable special handling and disposal procedures
- Carton includes one sterile single dose of INLEXZO™ co-packaged with one sterile urinary catheter and one sterile stylet



PATIENT COUNSELING INFORMATION

Advise patients to read the FDA-approved patient labeling (Patient Information)

Risk of Metastatic Bladder Cancer with Delayed Cystectomy

- Inform patients that delaying cystectomy could lead to development of metastatic bladder cancer. Discuss the risk of metastatic bladder cancer and that the risk increases the longer cystectomy is delayed in the presence of persistent CIS

Magnetic Resonance Imaging (MRI) Safety

- Inform patients that INLEXZO™ can only be safely scanned with MRI under specific conditions. Instruct patients who will have an MRI to tell their healthcare provider that they have INLEXZO™
- This information is included in the MRI Safety Information Card. Complete the MRI Safety Information Card and give it to the patient

IMPORTANT SAFETY INFORMATION

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.



PATIENT COUNSELING INFORMATION (continued)

Embryo-Fetal Toxicity

- Advise females of reproductive potential of the potential risk to a fetus and to inform their healthcare provider of a known or suspected pregnancy
- Advise females of reproductive potential to use effective contraception during treatment and for 6 months after final removal of INLEXZO™
- Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after final removal of INLEXZO™

Lactation

- Advise women not to breastfeed during treatment and for 1 week after final removal of INLEXZO™

Infertility

- Advise males of reproductive potential that INLEXZO™ may impair fertility

Important Post-Treatment Instructions

- Instruct patients not to empty the bladder immediately prior to the insertion procedure
- Advise patients to avoid contact with urine while INLEXZO™ is indwelling in the bladder and for at least 24 hours post-removal
- Advise patients to avoid urine contact with skin by voiding sitting on a toilet, flushing the toilet after use, and to wash hands with soap and water and to wash their genital area with water after each urination
- Advise patients to wash clothing soiled with urine promptly and separately from other clothing

CIS, carcinoma *in situ*; FDA, Food and Drug Administration; MRI, magnetic resonance imaging. INLEXZO™ [Prescribing Information]. Horsham, PA; Janssen Biotech, Inc.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (continued)

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.

Please see [Important Safety Information](#) on pages 28-29, and full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.





Important Safety Information

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.

WARNINGS AND PRECAUTIONS

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Please read full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™

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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 aminotransferase; AST, aspartate aminotransferase; BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; MRI, magnetic resonance imaging.
INLEXZO™ [Prescribing Information]. Horsham, PA; Janssen Biotech, Inc.

Please read full [Prescribing Information](#) and [Instructions for Use](#) for INLEXZO™.

Healthcare Provider Resources

Discover more at
INLEXZOhcp.com



Click here to visit the website or scan here to display on your device.
Data rates may apply.

Learn about [access & reimbursement](#)



Click here to visit the website or scan here to display on your device.
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Patient Resources

Care navigators, support and resources are available for your INLEXZO™ patients

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INLEXZO.com



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IMPORTANT SAFETY INFORMATION USE IN SPECIFIC POPULATIONS

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Market Access Resources

Johnson & Johnson Is Committed to Ensuring INLEXZO™ Fits Into Your Practice

Dual Procurement Pathways

Purchase INLEXZO™ your way

Specialty Pharmacy

Fulfillment through Accredo for tailored patient support

Specialty Distributor

Procure from our list of trusted Specialty Distributors

Dedicated Account Teams

Your Oncology Team at Johnson & Johnson is here to assist you and your patients

- Sales Representative
- Clinical Educator
- Field Reimbursement Manager
- Account Manager
- Medical Science Liaison

Access Resources

Tools and resources designed to educate and simplify the reimbursement process

- Access and Reimbursement Guide
- How to Order Guide
- Coding Flashcards
- In-Office Billing and Coding Support

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS (continued)

Lactation

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Females and Males of Reproductive Potential

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Geriatric Use

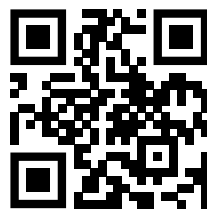
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Discover more at
INLEXZOhcp.com



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