Dosage and Administration of Intravesical Therapies for BCG-UR NMIBC With CIS ± Papillary Tumors

Please read full **Prescribing Information** and **Instructions for Use** for INLEXZO™

	INLEXZO[1]* (Gemcitabine intravesical system)	ADSTILADRIN[2] (nadofaragene firadenovec-vncg)	ANKTIVA + BCG[3] (nogapendekin alfa inbakicept-pmln)	Gemcitabine/Docetaxel[4–7]
Indication	BCG-UR NMIBC with CIS ± papillary tumors	HR BCG-UR NMIBC with CIS ± papillary tumors	BCG-UR NMIBC with CIS ± papillary tumors	***Not FDA approved for BCG-UR NMIBC**; AUA recommended for patients who are unfit or unwilling to undergo cystectomy and/or have BCG-UR disease*
Dosage frequency	Once every 3 weeks up to 6 months (8 doses), followed by once every 12 weeks for up to 18 months (6 doses)	Once every 3 months†	*Induction:* QW for 6 weeks‡ *Maintenance:* QW for 3 weeks at months 4, 7, 10, 13 and 19. Additional maintenance may be administered QW for 3 weeks at months 25, 31, and 37§	6 doses over 6 weeks and monthly maintenance for 2 years¶
Indwelling period	3 weeks	1 hour	2 hours**	Gem: 1–1.5 hours¶ Doce: 1–2 hours¶
Handling and Premedication considerations	INLEXZO should be inserted and removed by a trained HCP. Prophylactic antibiotics may be used at the discretion of the treating HCP during insertion and removal. INLEXZO is a hazardous drug, follow applicable special handling and disposal procedures	Premedication with an anticholinergic is recommended. All vials must be thawed‡‡ and brought to room temperature prior to use. Do not expose to higher temperatures. Protect from light. Do not refreeze. Biohazard handling procedures required	Admixture of ANKTIVA in combination with BCG must be used within 2 hours	Requires preparation of solutions by clinical pharmacist or nurse and strict safety measures, including proper disposal, availability of spill kits, and training of staff

INLEXZO Contraindications, Warnings and Precautions[1]

INLEXZO Contraindications

INLEXZO is contraindicated in patients with:

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

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, seven 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 94.0 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.

*Previously referred to as TAR-200. †In clinical studies, patients without evidence of HG recurrence were allowed to continue ADSTILADRIN treatment every 3 months after the first 12 months of treatment. ‡A second induction course may be administered if complete response is not achieved at Month 3. §The recommended duration of treatment is until disease persistence after second induction, disease recurrence or progression, unacceptable toxicity, or a maximum of 37 months. ¶Dwell times and dosing regimens vary depending on institutional protocol. **Patients unable to retain the suspension for 2 hours should be allowed to void sooner ‡‡Vials will thaw in approximately 3–5 hours at room temperature, or 4–5 hours in the refrigerator (subsequent time to bring thawed refrigerated vials to room temperature is approximately 2 hours 30 minutes). AUA, American Urological Association; BCG, Bacillus Calmette-Guérn; CIS, carcinoma *in situ*; Doce, docetaxel; FDA, United States Food and Drug Administration; Gem, gemcitabine; HCP, healthcare provider; HG, high-grade; HR, high risk; MRI, magnetic resonance imaging; NMIBC, non-muscle-invasive bladder cancer; QW, once a week; UR, unresponsive; USPI, United States prescribing information.

1. INLEXZO® (Gemcitabine intravesical system) [US Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2025. 2. ADSTILADRIN. Prescribing Information. Ferring Pharmaceuticals, Inc; August 2024. 3. ANKTIVA (nogapendekin alfa inbakicept-pmln) [Prescribing information]. Culver City, CA. ImmunityBio, Inc. 2024. 4. AUA. Intravesical Administration of Therapeutic Medication for the Treatment of Bladder Cancer. Revised June 2020. Available at: https://www.auanet.org/about-us/aua-statements/intravesical-administration-of-therapeutic-medication. 5. Holzbeierlein J, et al. Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline: 2024 amendment. *J Urol*. 2024;10.1097/JU.0000000000003846. 6. Steinberg RL, et al. *J Urol*. 2020;203:902-909. 7. McElree IM, et al. *JAMA*. 2023;6(2):e230849.

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