Jelmyto®
(mitomycin) for pyelocalyceal solution

SPARE THE KIDNEY FOR TOMORROW WITH JELMYTO*

The first and only FDA-approved treatment for low-grade upper tract urothelial carcinoma (LG-UTUC) in adult patients is an essential part of kidney-sparing management[1]*

Recognized by[2,3]

- **The American Urological Association (AUA)/ Society of Urologic Oncology (SUO) Guideline for non-metastatic UTUC**
- **NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)**

*JELMYTO is instilled via the pyelocalyceal system in a procedure that spares the kidney.

Indications and Usage

JELMYTO® (mitomycin) for pyelocalyceal solution is indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).

Important Safety Information

Contraindications

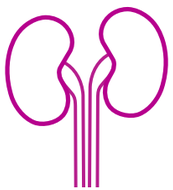
JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

The AUA/SUO Guideline for non-metastatic UTUC recognizes JELMYTO as part of a kidney-sparing approach to LG-UTUC management[2]

AUA/SUO RECOMMENDED

The AUA/SUO Guideline recommends tumor ablation for the initial management of low-risk,* favorable† UTUC (Strong Recommendation‡; Evidence Level: Grade B§). In certain clinical situations, chemoablation with JELMYTO® (mitomycin) for pyelocalyceal solution is recommended[2]



JELMYTO is included as part of kidney-sparing management, particularly in scenarios involving

- Location and focality challenges
- Patients for whom age, comorbidities, baseline renal function, and/or procedural risk are considerations

The benefits of JELMYTO must be balanced against the risk of ureteral stricture‖

*Low-grade tumors.

†Includes negative cytology, no invasion, no obstruction, normal nodes, unifocal, papillary, no involvement.

‡Strong recommendation: Net benefit or harm substantial.

§Moderate certainty.

‖In the OLYMPUS Study, ureteric obstruction events were reported in 58% of patients, which included ureteric stenosis in 44% of patients. Most events were grade 1 or 2.

"The advent of new therapies such as reverse thermo-hydrogel preparation of mitomycin have provided an important new means of treating low-risk tumors."

– Coleman et al[2]

Important Safety Information (continued)

Ureteric Obstruction

Ureteric obstruction, including ureteral stenosis and hydronephrosis, occurred in patients receiving JELMYTO. Monitor patients for signs and symptoms of ureteric obstruction, including flank pain, and fever, and for changes in renal function. Patients who experience obstruction may require transient or long-term ureteral stents or alternative procedures. Withhold or permanently discontinue JELMYTO based on the severity of ureteric obstruction.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

NCCN Guidelines® for Upper GU Tract Tumors

NCCN RECOMMENDED¶

National Comprehensive Cancer Network® (NCCN®) recommends mitomycin for pyelocalyceal solution (JELMYTO) following complete or near complete endoscopic resection as a primary therapy option for upper tract tumors[3#]

MOST SUITABLY INDICATED FOR:

a residual, low-grade, low volume (5-15 mm), solitary tumor in the upper urinary tract

a patient not a candidate for or not seeking nephroureterectomy as a definitive treatment

Mitomycin for pyelocalyceal solution may be administered via ureteral catheter or a nephrostomy tube. Complete or near complete endoscopic resection or ablation is recommended prior to mitomycin ureteral gel application.

¶Category 2A recommendation. **Category 2A:** Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate. All recommendations are Category 2A unless otherwise indicated.

#See NCCN Guidelines Bladder Cancer (Version 3.2023) Intrapelvic and Intravesical Therapy for Upper Tract Tumors and NCCN Guidelines for Upper GU Tract Tumors (Version 3.2023) for detailed recommendations.

To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

Important Information on the use of JELMYTO following endoscopic ablation

- JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract
- Due to risks associated with JELMYTO treatment, including the risk of bone marrow suppression, JELMYTO should not be instilled immediately following resection or ablation of low-grade UTUC. Please refer to the NCCN Guidelines and the AUA/SUO Guideline for principles of instillation therapy
- Patients treated in the OLYMPUS Study were required to have at least one measurable papillary tumor 5 to ≤ 15 mm prior to JELMYTO treatment. Twenty-six patients (37%) treated with JELMYTO in the OLYMPUS trial underwent tumor debulking via endoscopic ablation during the 6 weeks preceding enrollment in order to meet the study's tumor size criteria. The use of JELMYTO as an adjuvant to complete endoscopic ablation was not investigated in the OLYMPUS Study and, to date, has not been studied in a well-designed, prospective clinical trial

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THE AUA/SUO GUIDELINE STRONGLY RECOMMENDS KIDNEY-SPARING MANAGEMENT IN LG-UTUC[2]

Important Safety Information (continued)

Bone Marrow Suppression

The use of JELMYTO can result in bone marrow suppression, particularly thrombocytopenia and neutropenia. The following tests should be obtained prior to each treatment: Platelet count, white blood cell count differential and hemoglobin. Withhold JELMYTO for Grade 2 thrombocytopenia or neutropenia. Permanently discontinue for Grade 3 or greater thrombocytopenia or neutropenia.

Embryo-Fetal Toxicity

Based on findings in animals and mechanism of action, JELMYTO can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of mitomycin resulted in teratogenicity. Advise females of reproductive potential to use effective contraception during treatment with JELMYTO and for 6 months following the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with JELMYTO and for 3 months following the last dose.

Common Adverse Reactions

The most common adverse reactions in ≥ 20% of patients treated with JELMYTO were ureteric obstruction, flank pain, urinary tract infection, hematuria, abdominal pain, fatigue, renal dysfunction, nausea, dysuria, and vomiting.

Additional Adverse Reactions Information

Selected clinically relevant adverse reactions in < 10% and ≥ 2% of patients who received JELMYTO include urinary tract inflammation, bladder spasm, urosepsis, hypersensitivity, and instillation site pain.

Use in Specific Populations

Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with JELMYTO and for 1 week following the last dose.

Preparation and Administration Information

JELMYTO is for pyelocalyceal use only and not for intravenous use, topical use, or oral administration. JELMYTO must be prepared and administered by a healthcare provider. To ensure proper dosing, it is important to follow the preparation instructions found in the JELMYTO Instructions for Pharmacy and administration instructions found in the JELMYTO Instructions for Administration.

JELMYTO may discolor urine to a violet to blue color following the instillation procedure. Advise patients to avoid contact with urine for at least six hours post-instillation, to void urine sitting on a toilet, and to flush the toilet several times after use.

JELMYTO is a hazardous drug. Follow applicable special handling and disposal procedures.

Please see accompanying Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

References: 1. JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2022. **2.** Coleman JA, Clark PE, Bixler BR, et al. Diagnosis and management of non-metastatic upper tract urothelial carcinoma: AUA/SUO guideline. *J Urol.* 2023;209(6):1071-1081. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Bladder Cancer V.3.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed May 25, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.

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UroGen® Pharma