Jelmyto®
(mitomycin) for pyelocalyceal solution

JELMYTO® is an innovative treatment option and your partner in treating low-grade upper tract urothelial cancer (LG-UTUC)

- JELMYTO is an innovative treatment option for adults with LG-UTUC. LG-UTUC is a rare cancer that occurs in the lining of the kidneys and ureters.[1,2]
- Over half of patients who received JELMTYO achieved complete response in the Phase 3 OLYMPUS study and JELMYTO demonstrated durable, complete response at 12 months.[1]
- Data from a long-term follow-up study from a subset of patients from the OLYMPUS study showed a median duration of response of nearly four years in patients who achieved a complete response with JELMYTO.[4]
- Multiple clinical guidelines support the use of JELMYTO for kidney-sparing treatments.[5,6,7]
- JELMYTO is an innovative chemotherapy that is administered directly into the affected area of the kidney and stays there for 4-6 hours exposing the tumors to mitomycin. It does not go through the whole body like traditional chemotherapy.[1]
- JELMYTO is given as an outpatient treatment and patients typically are sent home the same day.
- JELMYTO treatment is administered at a clinic, hospital, or ambulatory surgery center once a week for 6 weeks. Anesthesia or a sedative may be used but is not required.[1,2]
- JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract. The most serious side effects of JELMYTO include: ureteric obstruction, bone marrow suppression, and embryo-fetal toxicity. The most common adverse reactions in ≥ 20% of patients treated with JELMYTO were ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, nausea, abdominal pain, fatigue, dysuria, and vomiting. Please see Full Prescribing Information for JELMYTO and Important Safety Information below.

Phase 3 OLYMPUS study showed[1]:

58% of patients had their tumors disappear after treatment with JELMYTO

3 months — 1 year

59%
of patients with unresectable tumors achieved comparable complete response rates at 3 months[2]

56%
of the patients who had their tumors disappear were still tumor free

New data from a long-term follow-up study in a subset of patients from the OLYMPUS trial showed patients remained in complete response for a median of nearly 4 years. Study limitations include post hoc analysis and inherent selection bias for the 20 patients that enrolled in the trial.[4]

Innovative RTGel® technology makes a sustained release possible, achieving prolonged exposure to treatment[1]:

JELMYTO combines mitomycin with a reverse-thermal hydrogel technology. With this innovative RTGel® technology JELMYTO fills the hard-to-reach places in the upper urinary tract.

Locally administered by ureteral catheter or a nephrostomy tube, JELMYTO is instilled as a chilled liquid, and RTGel® technology allows it to fill and conform to the renal pelvis as a semisolid gel.

After conversion to gel form, JELMYTO delivers sustained exposure to mitomycin with a dwell time of 4 to 6 hours before it slowly dissolves and exits the body through normal urine flow.

Some participants in the OLYMPUS trial were newly diagnosed and more than half had been treated for LG-UTUC in the past. Some of them had very hard-to-reach tumors that could not be removed with endoscopic management (minor surgery) alone. In the OLYMPUS study (n = 71), JELMYTO was instilled using a ureteral catheter once a week for 6 weeks.[1,2]

- JELMYTO has a well-established safety profile that is consistent across the heterogenous population with low-grade upper tract urothelial cancer studied in clinical trials and real-world analyses.[3,5]
- JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract. The most serious side effects of JELMYTO include: ureteric obstruction, bone marrow suppression, and embryo-fetal toxicity. The most common adverse reactions in ≥ 20% of patients treated with JELMYTO were ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, nausea, abdominal pain, fatigue, dysuria, and vomiting. Please see Full Prescribing Information for JELMYTO and Important Safety Information below.

UroGen Support™: to help patients get access to JELMYTO

UroGen Support™ may help identify financial assistance programs for patients with commercial, Medicare, or Medicaid coverage, as well as those with no insurance coverage. The appropriate program will depend on the patient's coverage and eligibility.

Additionally, **UroGen Support**™ offers billing and coding guidance for healthcare professionals to help ease access burdens.

JELMYTO® Indication and HCP Important Safety Information

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® (mitomycin) for pyelocalyceal solution is contraindicated in patients with perforation of the bladder or upper urinary tract.

Warnings and Precautions

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.

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.

Adverse Reactions

Common Adverse Reactions

The most common adverse reactions in ≥ 20% of patients treated with JELMYTO were ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, nausea, abdominal pain, fatigue, 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 visit Jelmyto.com for Full Prescribing Information, Instructions for Pharmacy and Instructions for Administration.

JELMYTO.COM

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UroGen® Pharma

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2. Kleinmann, N., et al., Primary chemoablation of low-grade upper tract urothelial carcinoma using UGN-101, a mitomycin-containing reverse thermal gel (OLYMPUS): an open-label, single-arm, phase 3 trial. Lancet Oncol, 2020. 21(6): p. 776–85.
3. Woldu, S.L., et al., Early experience with UGN-101 for the treatment of upper tract urothelial cancer - A multicenter evaluation of practice patterns and outcomes. Urol Oncol, 2023. 41(3): p. 147.e15–147.e21.
4. Pierorazio PM, Kleinmann N, Shabsigh A, et al. Long-Term Outcomes of Primary Chemoablation of Low-Grade Upper Tract Urothelial Carcinoma With UGN-101, a Mitomycin Reverse Thermal Gel. J Urol. 2024;0(0). doi:10.1097/JU.0000000000004331.
5. 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.
6. Rouprêt, M., et al., EAU Guidelines on Upper Urinary Tract Urothelial Cell Carcinoma. 2023: EAU Guidelines Office, Arnhem, The Netherlands.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Bladder Cancer version 1.2024. 2024 31 January 2024]; Available from: https://www.nccn.org/login?ReturnURL=https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf