Jelmyto®
(mitomycin) for pyelocalyceal solution

Communications Toolkit

Resources for Tailored JELMYTO Communication

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).

Contraindications

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

UroGen® Pharma

Welcome

This Communications Toolkit offers essential resources to help you share information about JELMYTO® (mitomycin) for pyelocalyceal solution. It includes customizable templates designed for educating local urologists, and for sharing these resources with healthcare providers and patients within your facility.

If you have any questions about the Communications Tool Kit, please contact your local JELMYTO representative.

JELMYTO Communications Toolkit

- Toolkit Overview
- Background on JELMYTO
- Resources for Healthcare Providers
- Public Relations Guidance and Template Materials
- JELMYTO Important Safety Information
- JELMYTO Full Prescribing Information
- Appendix

JELMYTO Key Points

- JELMYTO is an innovative chemotherapy used to treat adults with low-grade upper tract urothelial cancer (LG-UTUC).[1] LG-UTUC is a rare cancer that occurs in the lining of the kidneys and ureters known as the urothelium[1,2]
- JELMYTO is proven to help eliminate tumors in low-grade upper tract urothelial cancer, providing an alternative to minor surgery or endoscopic management which may lead to recurrence, or major surgery known as radical nephroureterectomy (RNU), which may carry the potential for long-term complications.[2,3]
- JELMYTO combines mitomycin with a reverse-thermal hydrogel technology administered directly into the affected area of the kidney once-weekly for 6 weeks and stays there for 4 to 6 hours. It does not go through the whole body like traditional chemotherapy.[1]
- In the Phase 3 OLYMPUS study (n=71) some participants were newly diagnosed and more than half had been treated for LG-UTUC in the past. Results show that 58% of patients had their tumors disappear after treatment with JELMYTO when given once a week for 6 weeks.[1]
- JELMYTO demonstrated durable, complete response at 12 months with 56% of patients remaining in complete response.[1]
- 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.[4]
- Multiple clinical guidelines support the use of JELMYTO for kidney-sparing treatment.[5,6,7]
- 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]

- 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.[1]

For more information on JELMYTO, please see the Full Important Safety Information below and refer to the Full Prescribing information, which is available as a download here.

Resources For HCPs

The following resources are available to inform and educate local HCPs and community members about JELMYTO.

JELMYTO Backgrounder

The JELMYTO Backgrounder offers an overview of JELMYTO, its innovative technology, and key data from the Phase 3 OLYMPUS trial and real-world evidence. It's ready for distribution as-is but can also be copied and pasted on to your institution's letterhead.

Download the JELMYTO Backgrounder

JELMYTO Referral Tracker

Treating complex diseases often requires a team approach. Some urology practices may not be equipped to administer JELMYTO for low-grade upper tract urothelial cancer, making referral a viable option. This downloadable referral tool can assist with the referral process and ensure continuity of care for patients.

Download the JELMYTO Referral Tracker

Public Relations Guidance

You have an exciting story to tell as a leading center for urologic care and one of the facilities in your community to offer JELMYTO, a treatment alternative in the treatment of adult patients with low-grade upper tract urothelial cancer. The following resources may be used within your facility to help create your own communications, educate the healthcare community and local media and/or to respond to potential media inquiries. Please work with your internal communications team for review and approval of this content as needed.

Press Release Template

The Press Release template can be customized to announce the availability of JELMYTO at your institution and your expertise. Simply insert your logo or paste it into your letterhead and personalize it as needed for distribution.

Download the Press Release Template

Internal Communications Template

The Internal Communications template can be customized to highlight your facility's commitment to patient care and therapies like JELMYTO. Insert your logo or paste it into your letterhead and personalize it for print or electronic distribution. It complements the Press Release.

Download the Internal Communications Template

Social Media Guidance

The Social Media Guidance document offers basic tips and sample posts for your accounts. Personalize and get your facility's approval before sharing.

Download the Social Media Guidance

Content for External Communications About JELMYTO

This document offers an overview of low-grade upper tract urothelial cancer and JELMYTO. Use it to craft external communications and handle media inquiries. Use this document as is or put it on your letterhead. It's for internal use only and should not be distributed externally.

Download the Content for External Communications About JELMYTO

JELMYTO Healthcare Provider and Patient Testimonials

Real-life experiences can effectively educate local urologists about JELMYTO. Use testimonials from staff and patients on your website and other media. Ensure you consult with your legal department for required disclosures and consent.

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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.

For more information on JELMYTO, please click here for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

Preserving Your Independence

Your institution has sole discretion in using content from this Communications Toolkit and owns all developed education materials. UroGen encourages including JELMYTO safety information and FDA-approved labeling in educational materials and suggests consulting your institution's legal department. The Communications Toolkit aims to educate and facilitate patient access to JELMYTO, without inducing or rewarding your institution for prescribing or recommending it.

Appendix

OLYMPUS Study design: The efficacy of JELMYTO was investigated in the OLYMPUS Study (N=71), a phase 3, open-label, single-arm, multicenter trial in patients with treatment-naïve or recurrent low-grade upper tract urothelial carcinoma (LG-UTUC) with ≥ 1 measurable papillary tumor 5 to ≤ 15 mm located above the ureteropelvic junction (partial tumor resection/debulking was permitted if > 15

mm). Patients received JELMYTO once weekly for 6 weeks. Complete response (CR) was defined as complete absence of tumor lesions in the ipsilateral pyelocalyceal system at 3 months after initiation of JELMYTO by urine cytology, ureteroscopy, and biopsy (if warranted). The primary endpoint was CR and the secondary efficacy endpoint was duration of response at 12 months.[1,2]

References:

1. JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2024.
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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, J.A., et al., Diagnosis and Management of Non-Metastatic Upper Tract Urothelial Carcinoma: AUA/SUO Guideline. J Urol, 2023. 209(6): p. 1071–81.
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