Not an actual patient.

Is there a durable option that can treat Mia's single low-grade tumor?

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

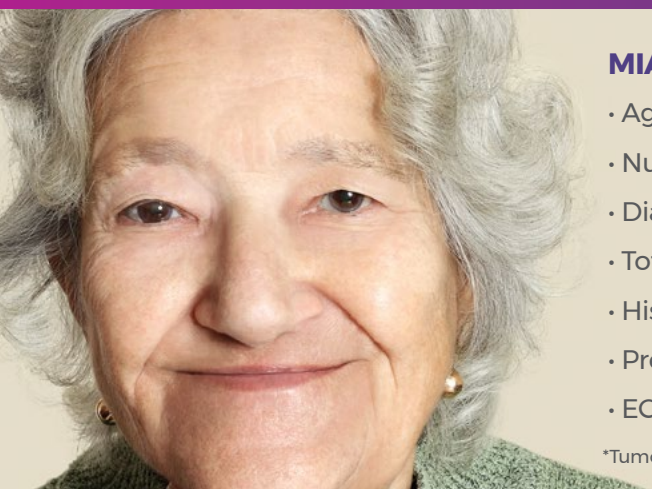
JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract.

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 click here for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

Jelmyto®
(mitomycin) for pyelocalyceal solution



MIA'S CHARACTERISTICS*

- Age: **76**
- Number of papillary tumors: **1**
- Diameter of largest tumor: **12 mm**
- Total tumor burden: **12 mm**
- History of LG-UTUC disease: **yes**
- Previous renal ablative surgery: **yes**
- ECOG PS: **1**

*Tumor characteristics based on latest UTUC diagnosis.

COMORBIDITIES

- CKD stage 3
- Hyperlipidemia

CASE HISTORY

- Mia has a history of urothelial carcinoma (UC). Two years ago she was treated with endoscopic ablation for a urethral tumor and was rendered disease free
- At 1 year Mia had a recurrence in the upper tract with a low-grade papillary tumor of 3 mm in the upper pole calyx of her right kidney. She was treated with ablation but developed postoperative vomiting from general anesthesia and a painful urinary tract infection
- Within 8 months Mia's CT scan showed a new, low-grade papillary tumor of 12 mm in the mid-portion of her left kidney. She is in need of a more definitive therapy — but with her existing comorbidities, radical nephroureterectomy could put her future health at risk[1,2]

†JELMYTO is instilled via the pyelocalyceal system in a procedure that spares the kidney.
CKD = chronic kidney disease; CT = computerized tomography; ECOG PS = Eastern Cooperative Oncology Group Performance Score; KM = Kaplan-Meier.

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 non-invasive UTUC with ≥ 1 measurable papillary tumor between 5-15 mm (partial resection/debulking was permitted if > 15 mm). Patients were treated with 6 instillations once a week. The dosage of JELMYTO was individualized based on volumetric measurements using pyelography with the intent to fill the renal pelvis (maximum dose was 15 mL or 60 mg mitomycin). 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. Secondary endpoint: durability of response at 12-month follow-up of CR evaluation.[3]

Important Safety Information (cont'd)

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.

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JELMYTO GIVES RECURRENT PATIENTS LIKE MIA A PATH FORWARD[3,4]

The OLYMPUS Study population included low-grade UTUC patients with similar characteristics to Mia[4,5]

- **52%** had history of LG-UTUC disease
- **52%** had previous renal ablative surgery
- **87%** had previous surgery related to UC
- **49%** had pre-existing hyperlipidemia
- **14%** had chronic kidney disease

Chemoablate with JELMYTO to spare Mia's kidney for tomorrow[3†]

- 58% of patients achieved complete response (CR) at 3 months (n=71; 95% CI: 45, 69)

82% durability of response at 12 months post-CR (95% CI: 66, 91)[3,6‡]

- Estimated probability by KM analysis that a patient will remain in CR for 12 months. At the 12-month assessment of durability (n=41): 23 patients remained in CR, 8 patients had a recurrence, and 10 patients were inevaluable
  - Median duration of response was not reached, with a range of 0-18.8+ months

Adverse reactions[3]

- 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

Instilled via catheter or nephrostomy tube as a chilled liquid once weekly for 6 weeks[3,4]

- Given as an outpatient procedure
- General anesthesia is not required
  - Used in 37% of patients for at least one instillation during the treatment period. Local anesthesia or sedation was used at the discretion of the physician

For patients like Mia,

CHEMOABLATE NOW, SPARE THE KIDNEY FOR TOMORROW[3†]

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Important Safety Information (cont'd)

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.

‡Kaplan-Meier analysis estimates probability of durable response. It does not represent an actual percentage of patients. In the OLYMPUS trial, at the time of the 12-month assessment for durability, not all patients had a recurrence (patients may have still been in CR, died, or discontinued). The KM analysis accounts for these missing data. The analysis has potential limitations: the sample size was small (n=41) and median duration of response was not reached due to the limited number of recurrences (n=8); this may be reflective of a short follow-up time (12 months).

References: 1. Lee KH, Chen YT, Chung HJ, et al. Kidney disease progression in patients of upper tract urothelial carcinoma following unilateral radical nephroureterectomy. *Ren Fail.* 2016;38(1):77-83. **2.** Trpkov K, Smith C, Patel P, Amin MB. Upper urinary tract urothelial carcinoma pathology. In: Shariat SF, Xylinas E, eds. *Upper Tract Urothelial Carcinoma*. Springer; 2015:45-89. **3.** JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2022. **4.** Kleinmann N, Matin SF, Pierorazio PM, 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):776-785. **5.** Data on file. UroGen Pharma, Inc., Princeton, NJ. **6.** Matin SF, Pierorazio PM, Kleinmann N, et al. Durability of response to primary chemoablation of low-grade upper tract urothelial carcinoma using UGN-101, a mitomycin-containing reverse thermal gel: OLYMPUS trial final report. *J Urol.* 2022;207(4):779-788.

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UroGen® Pharma

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