

# JELMYTO product information specification sheet



## Storage<sup>1</sup>

Store the JELMYTO carton at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. Avoid excessive heat over 40°C (104°F).

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

Dispensing pack	1 kit
NDC <sup>1</sup>	72493-103-03 or 72493-0103-03
Description <sup>1</sup>	Two 40 mg (each) single-dose vials of mitomycin for pyelocalyceal solution One 20 mL single-dose vial of sterile hydrogel to be used for reconstitution
HCPCS Level II code <sup>2*</sup>	J9281
WAC <sup>†</sup>	\$24,480 per carton



\*Content is informational only and does not constitute medical, legal, or reimbursement advice and represents no statement, promise, or guarantee of payment.

<sup>†</sup>WAC is subject to change at the election of UroGen.

HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code; WAC=wholesale acquisition cost.

JELMYTO is supplied in a single-dose carton containing 2 vials of sterile lyophilized mitomycin for pyelocalyceal solution, 40 mg each, and 1 vial of 20 mL of sterile hydrogel, to be used as a vehicle for reconstitution.<sup>1</sup>

Mitomycin for pyelocalyceal solution is a sterile, lyophilized, grey to greyish-purple cake or powder that contains mitomycin 40 mg and mannitol 80 mg in each vial.<sup>1</sup>

Sterile hydrogel is a sterile, clear, colorless gel with or without bubbles at room temperature or clear, colorless liquid at 2°C to 8°C (36°F to 46°F), which contains 0.04 g hydroxypropyl methylcellulose, 5.67 g poloxamer, 0.21 g polyethylene glycol, and water for injection in each vial.<sup>1</sup>

Once reconstituted, JELMYTO is a clear, purple, viscous liquid at 2°C to 8°C (36°F to 46°F) or semisolid gel at room temperature with a concentration of 4 mg/mL of mitomycin, which may contain a few visible particles and have a pH between 6.0 and 8.0.<sup>1</sup>

Please [click here](#) for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration for JELMYTO.



# UroGen Support is available to assist you and your eligible patients

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**Visit [www.JELMYTO.com/hcp/support](http://www.JELMYTO.com/hcp/support) to learn more about:**

- Comprehensive access and reimbursement support services
- Patient affordability and financial assistance for eligible patients. Additional restrictions and limitations may apply
- Product acquisition and preparation coordination

 855-JELMYTO (855-535-6986)

 833-664-7216

 [www.JELMYTO.com/hcp/support](http://www.JELMYTO.com/hcp/support)

Please [click here](#) for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration for JELMYTO.

**References:** 1. JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2024. 2. Centers for Medicare & Medicaid Services. CMS Healthcare Common Procedure Coding System (HCPCS) application summaries and coding decisions: third quarter, 2020 coding cycle for drug and biological products. Accessed November 6, 2024. <https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-3-2020-drugs-and-biologics.pdf>

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