

Medical Information Request: JELMYTO® (mitomycin) for pyelocalyceal solution.

Thank you for your request for information regarding the effect of JELMYTO and Sewer and Septic Systems.

The effects of JELMYTO on sewer or septic systems has not been systematically evaluated.

As described in the JELMYTO Prescribing Information [Ref.1]:

What are the ingredients of JELMYTO?

Active ingredient: mitomycin

Inactive ingredients: hydroxypropyl methylcellulose, mannitol, poloxamer, polyethylene glycol, and water for injection

Recommended Dosage

The dose of JELMYTO to be instilled is 4 mg per mL via ureteral catheter or a nephrostomy tube, with total instillation volume based on volumetric measurements using pyelography, not to exceed 15 mL (60 mg of mitomycin).

According to the Safety Data Sheet Jelmyto reconstituted. v2. [Ref. 2]:

- **SECTION 6: Accidental release measures**
 - **6.2 Environmental precautions**
 - Prevent entry into waterways, sewers, basements, or confined areas.
- **SECTION 13: Disposal considerations**
 - **13.1 Waste treatment methods**
 - **Product**
 - Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Please refer to the attachments below for detailed information on the preparation and administration of JELMYTO:

- INSTRUCTIONS FOR PHARMACY (IFP)
- INSTRUCTIONS FOR ADMINISTRATION (IFA)

Please refer to the package insert and www.jelmyto.com for the full Prescribing Information.

As described in the JELMYTO (mitomycin) for pyelocalyceal solution Prescribing Information:

- **INDICATIONS AND USAGE:** JELMYTO is an alkylating drug indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).
- **ADVERSE REACTIONS:** The most common adverse reactions (≥ 20%) are ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, nausea, abdominal pain, fatigue, dysuria, and vomiting.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit

<http://www.fda.gov/medwatch> or call 1-800-FDA-1088. You may also report side effects to UroGen Pharma at 1-855-987-6436.

References:

1. JELMYTO® (mitomycin) for pyelocalyceal solution. Prescribing Information 2024. UroGen Pharma, Princeton, New Jersey.
2. JELMYTO® Safety Data Sheet Jelmyto reconstituted. v2. Effective Date: 21-Dec-2022. Accessed December 18, 2024.
3. JELMYTO® and UroGen® are trademarks of UroGen Pharma, Ltd.



Attachments:

- JELMYTO® (mitomycin) for pyelocalyceal solution. Prescribing Information 2024
- JELMYTO® (mitomycin) for pyelocalyceal solution. Instructions for Pharmacy (IFP)
- JELMYTO® (mitomycin) for pyelocalyceal solution. Instructions for Administration (IFA)
- JELMYTO® (mitomycin) for pyelocalyceal solution. Safety Data Sheet Jelmyto reconstituted. v2.