

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

**Thank you for your request for information regarding the presence of latex in the packaging or formulation of JELMYTO.**

**Latex catheters or nephrostomy tubes made of latex should not be used during JELMYTO administration due risk of deformation attributed with pressure changes, which can impede flow of the hydrogel admixture.**

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

**How Supplied**

- JELMYTO kit –NDC 72493-103-03 OR 72493-0103-03
- JELMYTO is available in a kit containing the following:
  - Two 40 mg (each) single-dose vials of mitomycin for pyelocalyceal solution supplied as a sterile, lyophilized, grey to greyish-purple, cake or powder. (NDC 72493-101-40)
  - One 20 mL single-dose vial of sterile hydrogel supplied as 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), to be used as a vehicle for reconstitution. (NDC 72493-102-20)

The vials are made of glass and do not contain latex. The stoppers for the vials of mitomycin and the vial of sterile hydrogel are not made with natural rubber latex or dry natural rubber.

The UroGen Ureteral Catheter is a 7 Fr Ureteral Catheter with a fixed female luer lock hub. The catheter has an open tip, is 70 cm long and made of radiopaque polyurethan (20% BaSO<sub>4</sub>). The catheter is to be placed over a guidewire.

**Latex is not a declared component for either mitomycin, sterile hydrogel, or Urogen 7 French ureteral catheter.**

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](http://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. Data on file. UroGen Pharma.
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)