



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

Thank you for your question regarding the extended in use storage conditions and handling for reconstituted JELMYTO® (mitomycin) for pyelocalyceal solution.

Reconstituted JELMYTO® should be instilled as soon as possible after reconstitution. Store reconstituted JELMYTO at 20°C to 25°C (68°F to 77°F) **for up to 96 hours (4 days)**. JELMYTO® will appear as a semisolid gel when stored under these conditions. Protect reconstituted JELMYTO from light.

JELMYTO® must be instilled as a chilled solution using a Uroject12 Lever, a Luer Lock syringe, and a ureteral catheter with molded Luer Lock connector. Once chilled at -3°C to 5°C (27°F to 41°F), JELMYTO® will convert to a viscous liquid for instillation and is stable for up to 1 additional hour. Reconstituted JELMYTO® must be instilled within 1 hour after it is converted to a viscous liquid.

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

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, abdominal pain, fatigue, renal dysfunction, nausea, 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. [Package insert] Princeton, NJ; Revised September 2022. Urogen Pharma, Inc.

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

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

Attachments:

- JELMYTO® (mitomycin) for pyelocalyceal solution. Prescribing Information 2022
- JELMYTO® (mitomycin) for pyelocalyceal solution. Instructions for Pharmacy (IFP)
- JELMYTO® (mitomycin) for pyelocalyceal solution. Instructions for Administration (IFA)

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