

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

Thank you for your question regarding the administration of JELMYTO via Closed System Transfer Device (CSTD).

JELMYTO must be reconstituted by a healthcare professional prior to instillation. Reconstituted JELMYTO will appear as a semisolid gel and, once chilled, will convert to a viscous liquid for instillation.

UroGen recommends using of the Tevadaptor or OnGuard®2 CSTD as described in Instructions for Pharmacy (IFP) and Instructions for Administration (IFA) for JELMYTO. Tevadaptor or OnGuard®2 CSTD system was found to meet the requirements for a satisfactory flow of gel to facilitate the preparation and included a non-locking syringe adaptor, necessary to perform the instillation without CSTD.

Additionally, a functional test as well as chemical analysis found Equashield CSTD to be compatible with JELMYTO preparation when using the Chilling block (Model UCB0002) provided its wider dimensions compared to the original version (Model CB0001). An Equashield syringe adaptor should be procured for JELMYTO withdrawal from the admixture vial at the point of treatment, as this part is NOT supplied in the administration kit.

Additional Information:

The Tevadaptor Luer Lock Adaptor was tested with the instillation of JELMYTO using the following setup: Uroject12 Syringe Lever, Merit 20 mL syringe, Tevadaptor Syringe Adaptor, Tevadaptor Luer Lock Adaptor, UroGen 7 Fr Ureteral Catheter. The test followed instructions as outlined in the JELMYTO IFA and evaluated varying chilling temperatures (from -3 to 5 °C). Instillation with a CSTD following the JELMYTO IFA guidance and using the Tevadaptor Luer Lock Adaptor was determined as successful without any leaks or backflow in the syringe plunger.

UroGen has performed a preliminary evaluation of the BD PhaSeal™ system and found it incompatible with JELMYTO. Specifically, the flow of the sterile hydrogel through the adaptors is highly restricted. A longer time is subsequently required to withdraw from the vial and for the injection from the syringe resulting in solidification of the gel and clogging the system.

The ChemoLock™ CSTD was evaluated, and it was found that the adaptor for the syringe does not disconnect from the syringe. Although this CSTD did not impede product flow, it was noted as incompatible with the UroGen Chilling Block due to their respective configuration.

The Corvida Halo CSTD was not tested.

Your institution's use of this Additional Information is entirely within your institution's sole discretion. UroGen recommends only those pharmacy and administration supplies set forth in the IFP and IFA, respectively. The above Additional Information should not be construed as a recommendation, advice to pharmacists, or advice to other healthcare professionals.

Please refer to the INSTRUCTIONS FOR PHARMACY (IFP) and the INSTRUCTIONS FOR ADMINISTRATION (IFA) for JELMYTO® (mitomycin) for pyelocalyceal solution for detailed information on the preparation and administration of JELMYTO. Available from: <https://www.jelmyto.com>

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 ($\geq 20\%$) 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. The Tevadaptor[®] Luer Lock Adaptor. Accessed on January 25, 2021. Available from: <https://www.simplivia.com/products/tevadaptor/luer-lock-adaptor/>
4. B Braun Sharing Experience. Accessed on October 18, 2022. Available from: <https://www.bbraunusa.com/en/products/b5/onguard-2.html>
5. Equashield[®] Compounding Technologies. Accessed on October 18, 2022. Available from: <https://www.equashield.com/products/>.
6. JELMYTO[®] and UroGen[®] are trademarks of UroGen Pharma, Ltd. All other trademarks are the property of their respective owners.

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)
- Chilling Block (Model UCB002). Instructions for Use (IFU)