



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

Thank you for your request for information regarding cleaning of the new model of the Chilling Block (UCB0002) used in the preparation of JELMYTO® (mitomycin) for pyelocalyceal solution.

Cleaning and Disinfecting the Chilling Block after each use:

The Chilling Block device is compatible with PeridoxRTU®, a broad-spectrum sporicidal disinfectant or equivalent, as per your pharmacy's policy.

Please follow your pharmacy's policy regarding the application of the cleaning and disinfecting agents and appropriate steps to deactivate, decontaminate, clean, and disinfect as required, for example after use with hazardous materials or before aseptic use.

Disinfection efficacy testing was performed with PeridoxRTU® in accordance to recommended manufacturer's instructions and was found acceptable for all test microorganisms.

The new model of the Chilling Block (UCB0002) contains covered stainless-steel screws and aluminum canisters, which should not rust. The canisters are anodized and should not show corrosion. There could be some staining if not dried thoroughly after cleaning or if using strong base/alkali cleaning agents.

Please refer to the Full Prescribing Information for JELMYTO® at www.jelmyto.com and refer to the attachments listed below for detailed information on JELMYTO® preparation.

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.
2. Data on file. UroGen Pharma.
3. PeridoxRTU® (Sporicidal Disinfectant and Cleaner). Accessed on July 2nd, 2020. Available from: <https://www.contechealthcare.com/products/peridoxrtu-sporicidal-disinfectant-and-cleaner/> . Accessed September 22, 2022.
4. United States Pharmacopeia. USP General Chapter Hazardous Drugs– Handling in Healthcare Settings. 2020. Available from: <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare> . Accessed September 22, 2022.

Attachments:

- JELMYTO® (mitomycin) for pyelocalyceal solution. Prescribing Information 2022
- JELMYTO® (mitomycin) for pyelocalyceal solution. Instructions for Pharmacy (IFP)
- Chilling Block Instructions for Use (IFU)

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PeridoxRTU® is a trademark of CONTEC® HEALTHCARE.