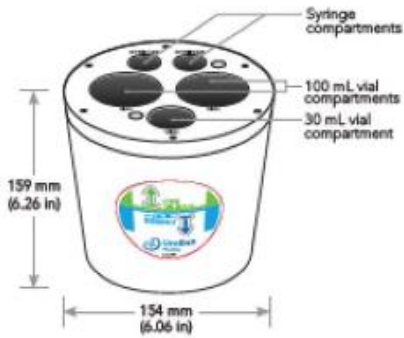
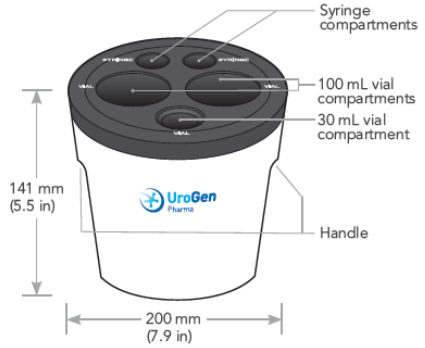


Medical Information Request: JELMYTO® (mitomycin) for pyelocalyceal solution.

Thank you for your request for information regarding updates made to the Chilling Block model used in the preparation of JELMYTO.

The Chilling Block is a portable chilling device designed to provide cooling of vials and syringes for at least 2 hours for a temperature of -3 °C to 5 °C (27 °F to 41 °F) for the preparation of JELMYTO. The following table outlines updates pertaining to the design, dimensions, and instructions prior to use between the Original Model CB0001 and Model UCB0002 Chilling Blocks:

| | Original Chilling Block (Model CB0001) | Chilling Block (Model UCB0002) |
|---------------------------|---|--|
| Design |  <p>Diagram of the Original Chilling Block (Model CB0001). It is a cylindrical container with a height of 159 mm (6.26 in) and a diameter of 154 mm (6.06 in). The top surface features four compartments: two labeled 'Syringe compartments', one labeled '100 mL vial compartments', and one labeled '30 mL vial compartment'.</p> |  <p>Diagram of the Chilling Block (Model UCB0002). It is a cylindrical container with a height of 141 mm (5.5 in) and a diameter of 200 mm (7.9 in). The top surface features four compartments: two labeled 'Syringe compartments', one labeled '100 mL vial compartments', and one labeled '30 mL vial compartment'. A 'Handle' is attached to the side of the container. The UroGen Pharma logo is visible on the front.</p> |
| Dimension | Height: 6.26" / Diameter: 6.06" | Height: 5.5" / Diameter: 7.9" |
| Instructions prior to use | Place chilling block, facing down, in the freezer at a temperature of -20 °C to -12 °C (-4 °F to 10.4 °F). | <p>12 hours before use place the Chilling Block (Model UCB0002) into a freezer at a temperature of -20 °C to -12 °C (-4 °F to 10.4 °F).</p> <p>Note the updated design of the Universal Chilling Block no longer requires upside down placement in freezer.</p> |

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 ($\geq 20\%$) 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. JELMYTO® and UroGen® are trademarks of UroGen Pharma, Ltd.

Attachments:

- JELMYTO® (mitomycin) for pyelocalyceal solution. Prescribing Information 2024
- Chilling Block (Model UCB002). Instructions for Use (IFU)