



INSTRUCTIONS FOR PHARMACY (IFP) JELMYTO™ (jel-MYE-toe) (mitomycin) for pyelocalyceal solution

Purpose of this Instructions for Pharmacy

This Instructions for Pharmacy contains information on how to prepare JELMYTO using pharmacy supplies and the UroGen Pharma Chilling Block.

Intended Use of JELMYTO

JELMYTO (mitomycin) for pyelocalyceal solution is indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).

Important Information You Need to Know Before Reconstituting JELMYTO

Once reconstituted with sterile hydrogel, JELMYTO will appear as a semisolid gel. Once chilled, JELMYTO will convert to a viscous liquid.

Reconstituted JELMYTO must be prepared under chilled conditions. A UroGen Pharma Chilling Block can be used for this purpose. JELMYTO cannot be prepared without the Chilling Block or other means of chilling.

Preparation of JELMYTO must be performed under aseptic conditions.

Storage Conditions and Handling

Instill the JELMYTO solution as soon as possible after reconstitution. If immediate instillation is not possible, store reconstituted JELMYTO at 20°C to 25°C (68°F to 77°F) for up to 8 hours. Protect from light.

JELMYTO is a cytotoxic anti-cancer drug. Procedures for Proper Handling and Disposal of anti-cancer drugs should be followed.

This "Instructions for Pharmacy" has been approved by the U.S. Food and Drug Administration.

TEVADAPTOR® is a registered trademark of Teva Medical Ltd.

Distributed by:

UroGen Pharma, Inc.
Princeton, NJ 08540
www.JELMYTO.com

JEL-IFP-001

IFP-0002025/Ver. 2

Supplies Needed:

JELMYTO Single-Dose Carton containing:

Do not substitute any of these components.

- 2 Vials of JELMYTO, 40 mg/vial
- 1 Vial Sterile Hydrogel, 20 mL/vial
- 1 JELMYTO Admixture Label
- JELMYTO Full Prescribing Information (PI)
- JELMYTO Instructions for Pharmacy (IFP)
- JELMYTO Instructions for Administration (IFA)

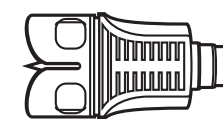


Pharmacy Supplies (Provided by Your Facility)

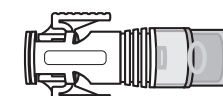
Do not substitute any of these components.

- 3 x TEVADAPTOR® Vial Adaptors
- 3 x TEVADAPTOR® Syringe Adaptors HF
- 1 x Luer Lock connector
- 2 x 10 mL Luer Lock syringes
- 1 x 20 mL Luer Lock syringe
- 1 x 20-25G needle (for drawing up sterile water)
- 2 mL sterile water
- 70% Isopropyl alcohol or equivalent
- 1 x Light protective bag
- 1 x UroGen Pharma Chilling Block

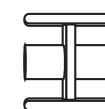
Note: The day before your preparation, put the Chilling Block in the freezer at -20°C to -12°C (-4°F to 10.4°F) upside down overnight. Please refer to the Chilling Block Instructions for Use for more information.



3 x TEVADAPTOR®
Vial Adaptor



3 x TEVADAPTOR®
Syringe Adaptor HF



1 x Luer Lock connector



1 x UroGen Pharma
Chilling Block

Frequently Asked Questions:

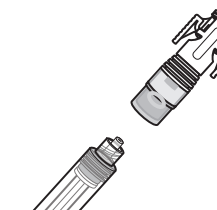
How do I connect the vial adaptor?

Place the vial adaptor over the vial and press down firmly. You will hear a snap which confirms successful attachment.



How do I connect the syringe adaptor?

Screw the Luer Lock end of the syringe adaptor onto the syringe hub until it is finger tight.



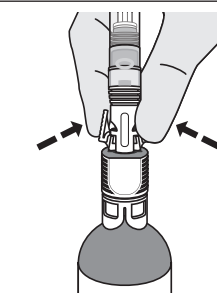
How do I connect the syringe adaptor to the vial adaptor?

Place the syringe adaptor over the vial adaptor and align the tabs, then press down firmly. You will hear a snap which confirms successful attachment.



How do I disconnect the syringe adaptor from the vial adaptor?

Pinch the tabs on the syringe adaptor to separate it from the vial adaptor.



Do I need to put the caps on the syringes and vials before placing them back into the chilling block?

YES, the chilling block inserts are not sterile. It is important to maintain aseptic technique.

Do I have to keep the vials upright when mixing? If so, why?

YES, the vials should be upright during all mixing to ensure the contents are fully mixed at the bottom of the vial.



I am having difficulty working with the drug product. It seems to be solidifying.

If you are having difficulty pushing the solution or withdrawing the solution, place the components back into the Chilling Block until the product liquifies.



Steps to Prepare JELMYTO Admixture

A FREEZE CHILLING BLOCK

- 1 The day before preparation, put the Chilling Block in the freezer at -20°C to -12°C (-4°F to 10.4°F) upside down overnight.

Note: Please refer to the Chilling Block Instructions for Use for additional information.

B PREPARE SUPPLIES

- 1 Remove the Chilling Block from the freezer.
- 2 Disinfect the Chilling Block by spraying it with 70% Isopropyl alcohol or equivalent. Allow it to air dry, and then place it upright inside the hood or isolator.
- 3 Wait 20 minutes before continuing.
- 4 Connect vial adaptors to all three vials.
- 5 Connect a syringe adaptor to one of the 10 mL syringes.
- 6 Connect a syringe adaptor to the 20 mL syringe.
- 7 Place the three vials, the 10 mL syringe, and the 20 mL syringe into the Chilling Block for at least 10 minutes.
- 8 While the vials and syringes are in the Chilling Block, withdraw 2 mL of sterile water into the other 10 mL syringe and set aside for later use.

C CREATE PRE-WETTING SOLUTION (PWS)

- 1 Slowly fill the chilled 20 mL syringe with 14 mL of sterile hydrogel.
- 2 Recap the chilled 20 mL syringe and place it in the Chilling Block.
- 3 Slowly fill the chilled 10 mL syringe with 4 mL of sterile hydrogel.
- 4 Discard the unused portion of sterile hydrogel.
- 5 Replace the needle on 2 mL sterile water syringe with the Luer Lock connector.
- 6 Remove the syringe adaptor from the 4 mL sterile hydrogel syringe.
- 7 Connect the 4 mL sterile hydrogel syringe to the other side of the Luer Lock connector on the 2 mL sterile water syringe.
- 8 Gently mix the sterile water with the sterile hydrogel by pushing the plungers back and forth at least 25 times to create the “pre-wetting solution” (PWS).
- 9 Transfer the 6 mL PWS into one of the syringes.
- 10 Replace the Luer Lock connector on the 6 mL PWS syringe with a new syringe adaptor.
- 11 Place the 6 mL PWS syringe in the Chilling Block.

D MIX THE ADMIXTURE

- 1 Remove both JELMYTO vials from the Chilling Block.
- 2 Gently tap the bottom of each vial on the table to ensure all the mitomycin powder is at the bottom of the vials.
- 3 Remove the chilled 6 mL PWS syringe from the Chilling Block.
- 4 Inject 3 mL of PWS into each JELMYTO vial.
Note: To ensure accurate dosing, the contents of each vial must be the same.
- 5 Discard the empty PWS syringe.
- 6 Gently swirl each JELMYTO vial upright at least 15 times, ensuring all powder and admixture is contained at the bottom of the vial.
Note: Do not invert or shake the vials.
- 7 Immediately remove the chilled 14 mL sterile hydrogel syringe from the Chilling Block.
- 8 Immediately inject 7 mL of sterile hydrogel into each JELMYTO vial.
Note: To ensure accurate dosing, the contents of each vial must be the same.
- 9 Gently swirl each JELMYTO vial upright at least 15 times, ensuring all admixture is contained at the bottom of the vial.
Note: Do not invert or shake the vials.
- 10 Recap and place the 20 mL syringe in the Chilling Block.
- 11 Mix the JELMYTO admixture vials:
 - Recap and place both JELMYTO vials in the Chilling Block for **five minutes**.
 - Remove both vials and vigorously swirl them upright at least 15 times, ensuring all admixture is contained at the bottom of the vials.
 - Place both vials back in the Chilling Block.
 - **Repeat these steps every five minutes for a total of 30 minutes.****Note:** Do not invert or shake the vials.

E PREPARE ADMIXTURE VIAL

- 1 Remove one JELMYTO vial from the Chilling Block.
- 2 Vigorously swirl the vial upright at least 15 times.
Note: Do not invert or shake the vial.
- 3 Using the chilled 20 mL syringe, slowly withdraw 7 mL of admixture from the vial.
Note: If you are having difficulty withdrawing the admixture, place the components back in the Chilling Block until the admixture liquifies again.
- 4 Discard the empty JELMYTO vial.
- 5 Remove the remaining JELMYTO vial from the Chilling Block.
- 6 Inject the contents of the 20 mL syringe into that vial. Now all the admixture is contained in one vial.
- 7 Recap the vial adaptor.
- 8 Vigorously swirl the vial upright at least 15 times.
Note: Do not invert or shake the vial.
- 9 Your JELMYTO admixture vial is now complete.

F DISPENSE ADMIXTURE VIAL

- 1 Write the “Discard after” date and time on the admixture label and apply to the prepared JELMYTO admixture vial.
Note: The “Discard after” date and time is 8 hours from the completion of the preparation at room temperature.
- 2 Place the following items in a light-protective bag:
 - JELMYTO admixture vial
 - JELMYTO Instructions for Administration
- 3 Transport to the treatment facility.



IMPORTANT TO REMEMBER

- All components must be kept cold during the preparation process by placing them in the Chilling Block when they are not in use.
- If you have difficulty pushing the solution or withdrawing the solution at any time, put the components back in the Chilling Block until the product liquifies.

