

NEPHROSTOMY TUBE PLACEMENT WITH KIDNEY VOLUME MEASUREMENT

A nephrostomy tube placement with kidney volume measurement is being requested by the provider below. This is for 6 planned instillations of chemotherapy (JELMYTO®) directly into the pyelocalyceal system.

PATIENT INFORMATION

Patient First Name, Middle Initial: _____

Last Name: _____

Birth Date: _____

Phone: _____ E-mail: _____

Face Sheet Enclosed

PRESCRIBING PHYSICIAN INFORMATION

Practice/Facility Name: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone: _____ Fax: _____

Office Contact: _____

Physician Signature: _____

Physician Name (Print): _____

A Clinical Nurse Educator (CNE) is available for any educational support needed for volumetric measurements and instillation. Contact UroGen Support™ at 1-855-JELMYTO (1-855-535-6986).

MEASURE THE KIDNEY VOLUME BEFORE THE FIRST INSTILLATION

The instillation volume will be equal to the patient's kidney volume. If the kidney volume is NOT known, or needs to be reassessed, use the following steps:

1. Perform an antegrade pyelogram using diluted contrast (50%) so that the entire renal pelvis and calyces are observed, and the contrast starts to flow below the ureteropelvic junction (UPJ).

Note: Slow administration of the contrast may facilitate a more accurate measurement since contrast could be drained into the ureter.

2. Record the volume of the contrast injected at this point.
3. Allow the contrast to drain from the kidney. This may take about 5 minutes.

Note: Do not withdraw contrast back into the syringe

4. Repeat Steps 1 through 3 two more times for a total of 3 measurements to improve accuracy.
5. Subtract 2 mL from each measurement prior to averaging to account for the internal dwell volume in the nephrostomy catheter (dead space).
6. Select the kidney volume OR 15 mL, whichever is lower, as the instillation volume.

Note: In UroGen's OLYMPUS Study, volumetric estimation with retrograde pyelography indicated between 5 and 15 mL of JELMYTO would be sufficient for full and even distribution of the gel insert. The median volumetric estimation was approximately 9 mL.¹

References: 1. Data on file. UroGen Pharma Inc., Princeton, NJ.

Please see next page for Full Important Safety Information.



NEPHROSTOMY TUBE ORDER INFORMATION

NOTE: Follow practice/institutional protocol regarding placement for nephrostomy tube and time allowance for healing before proceeding with JELMYTO® instillation

- A silicon or silastic percutaneous nephrostomy tube with molded Luer Lock connector and locking loop must be placed prior to instillation. **No latex due to risk of rupture.**

Nephrostomy Tube Placement Date: _____ Nephrostogram Date: _____

Volumetric Measurements: _____

Indications and Usage

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

Important Safety Information

Contraindications

JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract.

Ureteric Obstruction

Ureteric obstruction, including ureteral stenosis and hydronephrosis, occurred in patients receiving JELMYTO. Monitor patients for signs and symptoms of ureteric obstruction, including flank pain, and fever, and for changes in renal function. Patients who experience obstruction may require transient or long-term ureteral stents or alternative procedures. Withhold or permanently discontinue JELMYTO based on the severity of ureteric obstruction.

Bone Marrow Suppression

The use of JELMYTO can result in bone marrow suppression, particularly thrombocytopenia and neutropenia. The following tests should be obtained prior to each treatment: Platelet count, white blood cell count differential and hemoglobin. Withhold JELMYTO for Grade 2 thrombocytopenia or neutropenia. Permanently discontinue for Grade 3 or greater thrombocytopenia or neutropenia.

Embryo-Fetal Toxicity

Based on findings in animals and mechanism of action, JELMYTO can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of mitomycin resulted in teratogenicity. Advise females of reproductive potential to use effective contraception during treatment with JELMYTO and for 6 months following the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with JELMYTO and for 3 months following the last dose.

Common Adverse Reactions

The most common adverse reactions in $\geq 20\%$ of patients treated with JELMYTO were ureteric obstruction, urinary tract infection, hematuria, flank pain, nausea, dysuria, renal dysfunction, vomiting, fatigue, and abdominal pain.

Additional Adverse Reactions Information

Selected clinically relevant adverse reactions in $< 10\%$ and $\geq 2\%$ of patients who received JELMYTO include urinary tract inflammation, bladder spasm, urosepsis, hypersensitivity, and instillation site pain.

Use in Specific Populations

Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with JELMYTO and for 1 week following the last dose.

Preparation and Administration Information

JELMYTO is for pyelocalyceal use only and not for intravenous use, topical use, or oral administration. JELMYTO must be prepared and administered by a healthcare provider. To ensure proper dosing, it is important to follow the preparation instructions found in the JELMYTO Instructions for Pharmacy and administration instructions found in the JELMYTO Instructions for Administration.

JELMYTO may discolor urine to a violet to blue color following the instillation procedure. Advise patients to avoid contact with urine for at least six hours post-instillation, to void urine sitting on a toilet, and to flush the toilet several times after use.

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

Please [click here](#) for the Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration. Please [click here](#) for the INSTRUCTION GUIDE for Instillation of JELMYTO® (mitomycin) for pyelocalyceal solution with a nephrostomy tube.



JELMYTO® and UroGen® are registered trademarks and UroGen Support is a trademark of UroGen Pharma, Ltd.
© 2022 UroGen Pharma, Inc.
All rights reserved. US-JEL-00533 03/22

