

Medical Information Request: JELMYTO®(mitomycin) for pyelocalyceal solution.
Thank you for your question regarding the shelf life of the JELMYTO kit.

JELMYTO® is indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC). JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract.

As components are manufactured separately, and the final kit is assembled afterwards, the manufacturer verifies the expiration dates of the components at the labeling/kitting stage and assigns the label with the shortest expiration date out of the two components (sterile hydrogel and mitomycin), which is then defined as the expiration date for the kit as a whole.

The shelf life of the JELMYTO kit is up to 36 months, the same as for each of the components within the JELMYTO kit.

As described in the JELMYTO®(mitomycin) for pyelocalyceal solution Prescribing Information [Ref.1]:

How Supplied:

- JELMYTO kit – NDC 72493-103-03 **OR** 72493-0103-03
- JELMYTO is available in a kit containing the following:
 - Two 40 mg (each) single-dose vials of mitomycin for pyelocalyceal solution supplied as a sterile, lyophilized, grey to greyish-purple, cake or powder. (NDC 72493-101-40)
 - One 20 mL single-dose vial of sterile hydrogel supplied as a sterile, clear, colorless gel with or without bubbles at room temperature or clear, colorless liquid at 2°C to 8°C (36°F to 46°F), to be used as a vehicle for reconstitution. (NDC 72493-102-20)

Please refer to the package insert and www.jelmyto.com for the full Prescribing Information.

IMPORTANT SAFETY INFORMATION

Contraindications

JELMYTO® (mitomycin) for pyelocalyceal solution is contraindicated in patients with perforation of the bladder or upper urinary tract.

Warnings and Precautions

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.



Adverse Reactions

Common Adverse Reactions

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

Additional Adverse Reactions Information

Selected clinically relevant adverse reactions in $< 10\%$ and $> 2\%$ 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 hazardous drug. Follow applicable special handling and disposal procedures.

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.

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