Medical Information Request: ZUSDURI™ (mitomycin) for intravesical solution and Appropriate Disposal

Thank you for your request for additional information regarding the appropriate disposal of ZUSDURI.

ZUSDURI™ is indicated for the treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).

As described in the ZUSDURI Prescribing Information [Ref.1]:

How Supplied:
ZUSDURI is available in a kit (NDC 72493-106-03) containing the following:

- Two 40 mg (each) single-dose vials of mitomycin for intravesical solution supplied as a sterile, lyophilized, grey to greyish-purple, cake or powder. (NDC 72493-104-40)
- One single-dose vial of 60 mL 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 72493-105-60)

Recommended Dosage: The recommended dose of ZUSDURI is 75 mg (56 mL) instilled once weekly for six weeks into the bladder via a urinary catheter.

ZUSDURI is a hazardous drug. Follow applicable special handling and disposal procedures.

Waste must be disposed of in accordance with federal, state and local environmental control regulations. Empty containers should be taken for local recycling, recovery or waste disposal.

Follow applicable special handling and disposal procedures:

Please refer to OSHA Hazardous Drugs Guidelines for proper disposal of mitomycin [Ref. 5-6]:
https://www.osha.gov/etools/hospitals/pharmacy/disposal-of-hazardous-drugs
OSHA requires: Bags containing materials contaminated with hazardous drugs covered under the Hazard Communication Standard, must be labeled in accordance with Section F.

The most common waste streams used for point of generation pharmaceutical waste segregation are included below in Table 8 from Practice GreenHealth. Trace chemotherapy, including “RCRA” (Resource Containment and Recovery Act) empty vials of chemotherapy agents, syringes/needles, IVs, personal protective equipment (PPE) used to prepare or administer chemotherapy without visible contamination, should be placed in yellow bins.
https://www.hercenter.org/hazmat/tenstepblueprint.pdf [Ref. 7]

400 Alexander Park Drive, 4th Floor, Princeton, NJ 08540 | 646-768-9780

Table 8. Pharmaceutical Waste Streams (from Practice GreenHealth) [Ref. 7]

Type of Waste	Description of Waste	Description of Container	Type of Treatment
Hazardous Toxic and BMP Toxic	**P, U and toxic D wastes** **All bulk non-listed chemotherapy drugs** Non-listed toxic drugs PPE with visible contamination	**Black**	**Incineration at RCRA hazardous waste facility**
Hazardous Ignitable	D001 wastes	Black	Incineration at RCRA hazardous waste facility
Hazardous and Infectious	Hazardous toxic wastes and BMP toxic wastes combined with regulated medical waste (RMW) Entire contents of sharps containers if P-listed hazardous waste was properly or improperly discarded in container (NOTE: Recent expansion of the epinephrine syringe exemption should reduce this waste to a minimum if accepted by states.)	Black hazardous waste container in needlebox configuration with RMW label applied	Incineration at a facility permitted to handle RCRA hazardous waste and RMW
Trace Chemotherapy	**"RCRA" empty vials of chemotherapy agents, syringes/needles, IVs, PPE used to prepare or administer chemotherapy without visible contamination**	**Yellow**	**Incineration at RMW facility**
Drain Disposal	Controlled substances, NaCl, dextrose, vitamins, electrolytes	Sewer NOTE: An increasing number of states and municipalities are restricting drain disposal of drugs, including controlled substances.	Local POTW (permission required)
BMP Non-Regulated	All other drugs	White with blue top or cream with purple top	Incineration at RMW or municipal solid waste (MSW) facility

400 Alexander Park Drive, 4th Floor, Princeton, NJ 08540 | 646-768-9780

Additional Information:

- Thick, leak-proof plastic bags, colored differently from other hospital trash bags, should be used for routine collection of discarded gloves, gowns and other disposable material, and labeled as **Hazardous Drug-related wastes**.
- OSHA suggests the waste bag should be kept inside a covered waste container clearly labeled "Hazardous Drug WASTE ONLY." At least one such receptacle should be located in every area where the drugs are prepared or administered. Waste should not be moved from one area to another. The bag should be sealed when filled and the covered waste container taped. [Ref. 5-6]
    - **Hazardous Waste Disposal and Containers:** Please see the OSHA document "Controlling Occupational Exposure to Hazardous Drugs" for detailed information. Labeling items of hazardous waste as **Hazardous Drug Waste Only**.
    - These items should be disposed of in properly labeled, covered, and sealed disposal containers and handled by trained and protected personnel.
    - Since sharps and potentially infectious materials may also be included in the trace contaminated materials, such containers should be managed as biohazardous waste under the **Bloodborne Pathogens Standard**.
    - Hazardous drug-related wastes should be disposed of according to EPA, state and local regulations for hazardous waste.

Please refer to the Full Prescribing Information for ZUSDURI here.

ZUSDURI IMPORTANT SAFETY INFORMATION:

Contraindications

ZUSDURI is contraindicated in patients with perforation of the bladder or in patients with prior hypersensitivity reactions to mitomycin or any component of the product.

Warnings and Precautions

Risks in Patients with Perforated Bladder

ZUSDURI may lead to systemic exposure to mitomycin and severe adverse reactions if administered to patients with a perforated bladder or to those in whom the integrity of the bladder mucosa has been compromised. Evaluate the bladder before the intravesical instillation of ZUSDURI and do not administer to patients with a perforated bladder or mucosal compromise until bladder integrity has been restored.

Embryo-Fetal Toxicity

Based on findings in animals and mechanism of action, ZUSDURI 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 ZUSDURI and for 6 months following the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ZUSDURI and for 3 months following the last dose.

Adverse Reactions

Common Adverse Reactions

The most common (≥10%) adverse reactions, including laboratory abnormalities, that occurred in patients treated with ZUSDURI were increased creatinine, increased potassium, dysuria, decreased hemoglobin, increased aspartate aminotransferase, increased alanine aminotransferase, increased eosinophils, decreased lymphocytes, urinary tract infection, decreased neutrophils, and hematuria.

Additional Adverse Reactions Information

Clinically relevant adverse reactions occurring in <10% of patients who received ZUSDURI included increased urinary frequency, fatigue, urinary incontinence, urinary retention, urethral stenosis, genital pain, urinary urgency, genital edema, genital pruritus, genital rash, urethritis, acute kidney injury, balanoposthitis, and nocturia.

400 Alexander Park Drive, 4th Floor, Princeton, NJ 08540 | 646-768-9780

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 ZUSDURI and for 1 week following the last dose.

Preparation and Administration Information

ZUSDURI is to be administered by intravesical instillation only. Do not administer ZUSDURI by pyelocalyceal instillation or by any other route.

ZUSDURI must be prepared and administered by a healthcare provider. To ensure proper dosing, it is important to follow the preparation instructions found in the ZUSDURI Instructions for Pharmacy and administration instructions found in the ZUSDURI Instructions for Administration.

ZUSDURI may discolor urine to a violet to blue color following the instillation procedure. Advise patients for at least 24 hours post-instillation to avoid urine contact with skin, to void urine sitting on a toilet, and to flush the toilet several times after use. Advise patients to wash hands, perineum or glans with soap and water after each instillation procedure.

ZUSDURI 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.

Please see accompanying Full Prescribing Information, Instructions for Pharmacy and Instructions for Administration.

References:

1. ZUSDURI™ (mitomycin) for intravesical solution. Prescribing Information. UroGen Pharma; 2025.
2. ZUSDURI™ (mitomycin) for intravesical solution. Instructions for Pharmacy (IFP)
3. ZUSDURI™ (mitomycin) for intravesical solution. Instructions for Administration (IFA)
4. Chilling Block (Model UCB002). Instructions for Use (IFU)
5. Occupational Safety and Health Administration. “Controlling Occupational Exposure to Hazardous Drugs.” U.S. Department of Labor, *Occupational Safety and Health Administration.* Web. Accessed May 7, 2025. https://www.osha.gov/hazardous-drugs/controlling-occex#disposal
6. Occupational Safety and Health Administration. “Pharmacy Disposal of Hazardous Drugs.” U.S. Department of Labor, *Occupational Safety and Health Administration.* Web. Accessed May 7, 2025. https://www.osha.gov/etools/hospitals/pharmacy/disposal-of-hazardous-drugs
7. Pines E, Smith C, et al. “Managing Pharmaceutical Waste. A 10-Step Blueprint for Healthcare Facilities In the United States.” *Practice Greenhealth*. Web. Accessed May 7, 2025. https://www.hercenter.org/hazmat/tenstepblueprint.pdf
8. Data on file. UroGen Pharma.