



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

**Thank you for your question regarding the appropriate disposal for Jelmyto**

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

**What are the ingredients of JELMYTO?**

**Active ingredient:** mitomycin

**Inactive ingredients:** hydroxypropyl methylcellulose, mannitol, poloxamer, polyethylene glycol, and water for injection

**Recommended Dosage**

The dose of JELMYTO to be instilled is 4 mg per mL via ureteral catheter or a nephrostomy tube, with total instillation volume based on volumetric measurements using pyelography, not to exceed 15 mL (60 mg of mitomycin).

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

According to the JELMYTO Safety Data Sheet [Ref. 2]:

**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. 3]:**

<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" empty vials of chemotherapy agents, syringes/needles, IVs, PPE used to prepare or administer chemotherapy without visible contamination, should be placed in yellow bins.

<https://www.hercenter.org/hazmat/tenstepblueprint.pdf>

Table 8. Pharmaceutical Waste Streams (from Practice GreenHealth)

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 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

**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**.
- The Technical Chapter 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.
- **Hazardous Waste Disposal and Containers:** The [OSHA Technical Manual Part IV](#), Section C recommends:
  - Labeling items of hazardous waste as **Hazardous Drug waste only**.
  - The use of properly labeled, sealed and covered disposal containers, handled by trained and protected personnel, as required under the **Bloodborne Pathogens Standard** if such items are contaminated with blood or other potentially infectious materials.
  - Hazardous drug-related wastes should be disposed of according to EPA, state and local regulations for hazardous waste. This disposal can occur at either an incinerator or a licensed sanitary landfill for toxic wastes, as appropriate. Commercial waste disposal is performed by a licensed company. While awaiting removal, the waste should be held in a secure area in covered, labeled drums with plastic liners.

Please refer to the package insert and [www.jelmyto.com](http://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 (≥ 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® Safety Data Sheet Jelmyto Reconstituted. v2. Effective Date: 21-Dec-2022. Accessed January 22, 2024.
3. Occupational Safety and Health Administration. "Disposal of Hazardous Drugs." U.S. Department of Labor, *Occupational Safety and Health Administration*. Web. Accessed January 22, 2024.
4. JELMYTO® and UroGen® are trademarks of UroGen Pharma Ltd.