UroGen Pharma

INSTRUCTIONS FOR ADMINISTRATION (IFA)

ZUSDURI® (zus-dur-ee)

(mitomycin) for intravesical solution

FOR INTRAVESICAL INSTILLATION ONLY

⚠ **Read and follow this Instructions for Administration prior to each ZUSDURI instillation.**

Purpose of this Instructions for Administration

This Instructions for Administration contains information on how to instill ZUSDURI using the ZUSDURI vial and the devices listed under **Supplies Needed**, obtained by your facility.

Intended Use of ZUSDURI

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

Important Information You Need to Know Before Instilling ZUSDURI

ZUSDURI must be reconstituted by a healthcare professional prior to instillation. Reconstituted ZUSDURI will appear as a semisolid gel. Once chilled, ZUSDURI will convert to a viscous liquid for instillation.

Once instilled into the patient's bladder, ZUSDURI will convert to a semisolid gel, thereby exposing the lining of the bladder to mitomycin over a prolonged period of time.

Storage Instructions for Reconstituted ZUSDURI:

- Instill reconstituted ZUSDURI as soon as possible.
- If not used immediately, store reconstituted ZUSDURI:
  - under refrigeration at 2°C to 8°C (36°F to 46°F) for up to 7 days; or
  - under refrigeration at 2°C to 8°C (36°F to 46°F) for up to 6 days followed by no more than 24 hours at room temperature, 20°C to 25°C (68°F to 77°F).
- Discard 7 days after reconstitution.
- Protect from light.
- Avoid excessive heat over 40°C (104°F).

When ready to instill, chill ZUSDURI at -3°C to 5°C (27°F to 41°F) for about 20 minutes to revert it to a viscous liquid. See Steps A through C below for complete administration instructions.

ZUSDURI is a hazardous drug. Procedures for proper handling and disposal of hazardous drugs should be followed, as described below.

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

Distributed by:

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www.ZUSDURI.com

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OnGuard® is a registered trademark of Simplivia Healthcare Ltd.

BD Luer-Lok™ is a trademark of Becton, Dickinson and Company.

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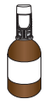
ZUS-IFA-001

Supplies Needed

One vial of reconstituted ZUSDURI, with resultant concentration of 80 mg per 60 mL.
(prepared and provided by your pharmacy)



Ice Bath

Note: The ice bath should consist of ice and cold water and be large enough to submerge a ZUSDURI vial.

Plastic Bag

Ancillary Supplies

When you administer ZUSDURI, you will need to use special adaptors for your catheter and syringes. These adaptors will create a closed pathway to protect you and your patient during and after administration. Fluid will only be able to pass between connection points when the adaptors are fully engaged, preventing drips or leaks.

Once the adaptors are connected, do not disconnect them. They are there for your protection.

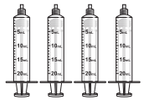
Urinary Catheter
One 12 Fr to 16 Fr with fixed Luer lock connector

- **Do not substitute**

Catheter Adaptor
One OnGuard®2 CSTD Luer lock adaptor

- **Do not substitute**

Administration Syringes
Four 20 mL polypropylene Luer lock syringes (BD Luer-Lok™ Syringe)



- **Do not substitute**

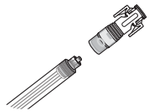
Sterile Water Flush
One 5 mL Luer lock syringe filled with 3 mL sterile water

Syringe Adaptors
Five OnGuard®2 CSTD syringe adaptors

- **Do not substitute**

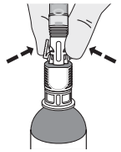
Frequently Asked Questions

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.



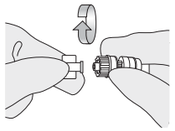
How do I connect the syringe adaptor to the vial adaptor?
Place the syringe adaptor over the vial adaptor and align the tabs; then press down firmly. You will hear a snap which confirms successful attachment.

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.

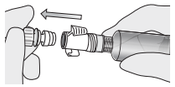


I am having a hard time working with ZUSDURI. It seems to be solidifying.
If you are having difficulty pushing or withdrawing ZUSDURI, recap and place the components back into the ice bath until ZUSDURI liquifies. The vial may be placed upside down within the bag in the ice bath.

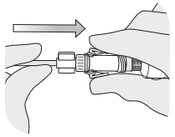
How do I connect the catheter adaptor to the urinary catheter?
Screw the Luer lock end of the catheter adaptor onto the urinary catheter connector until it is finger tight.



How do I connect the syringe adaptor to the catheter adaptor?
Place the syringe adaptor in front of the catheter adaptor and push it on firmly. You will hear a snap which confirms successful attachment.



How do I disconnect the syringe adaptor from the catheter adaptor?
While holding the urinary catheter steady and fixed in its position, pinch the tabs on the syringe adaptor to separate it from the catheter adaptor.



Turn Over for More Information

Zusduri® (mitomycin) for intravesical solution

Please click here for Full Prescribing Information.

Instillation Instructions

A CHILL THE ZUSDURI

1. Place the ZUSDURI vial in a plastic bag.
2. Place the plastic bag in the ice bath **for approximately 20 minutes.**

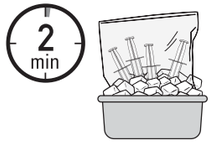
   Note: Ensure the ZUSDURI vial is completely immersed in the ice bath.

B PREPARE THE FOUR ADMINISTRATION SYRINGES

1. Connect a syringe adaptor to the 3 mL sterile water syringe and set aside.
2. Connect syringe adaptors to the four 20 mL syringes. These will be the administration syringes.

   Note: Once the adaptors are connected, do not disconnect them. They are there for your protection.
3. Remove the ZUSDURI vial from the ice bath and verify the admixture is liquid. If the admixture is not liquid, place the vial bag back into the ice bath until the admixture liquefies.
4. Swirl the vial upright to ensure that ZUSDURI is uniformly mixed.
5. Slowly fill each of the four administration syringes with 14 mL of ZUSDURI admixture (for a total of 56 mL).

   Note: There might be foaming in the syringe while withdrawing ZUSDURI.
6. Place the four administration syringes in the plastic bag.
7. Place the plastic bag in the ice bath, ensuring the four administration syringes are completely immersed, for at least two minutes.



C INSTILL ZUSDURI

- The contents of four administration syringes must be instilled in rapid succession without delay to avoid ZUSDURI solidification. Before proceeding:
  - Ensure that all four administration syringes contain liquid ZUSDURI.
  - Keep all four administration syringes chilled in the ice bath until instillation time.

1. Place the urinary catheter in the bladder and drain the urine.
2. Connect the catheter adaptor to the urinary catheter.
3. Connect an administration syringe to the urinary catheter.
4. Instill the ZUSDURI into the patient.

   Note: Empty each administration syringe over approximately 30 seconds. ZUSDURI is viscous, even in a chilled state.

5. Disconnect the syringe adaptor from the catheter adaptor.
6. **Immediately repeat these steps without delay** for the remaining three administration syringes.
7. After all four administration syringes have been instilled, flush the urinary catheter with 3 mL of sterile water.
8. Wait 15 minutes before removing the urinary catheter from the patient.

9. Discard all ancillary supplies according to your facility's procedures for hazardous waste.

Turn Over for More Information

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To learn more about ZUSDURI, visit ZUSDURI.com/hcp

Please click here for Full Prescribing Information.

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