



INSTRUCTIONS FOR PHARMACY (IFP)

ZUSDURI™ (zus-dur-ee)
(mitomycin) for intravesical solution

Purpose of this Instructions for Pharmacy

This Instructions for Pharmacy contains information on how to prepare ZUSDURI using pharmacy supplies and a Chilling Block or other means of chilling.

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 Reconstituting ZUSDURI

Reconstituted ZUSDURI must be prepared under chilled conditions. ZUSDURI cannot be prepared without a Chilling Block or other means of chilling. Once reconstituted with sterile hydrogel, ZUSDURI will appear as a semisolid gel under room temperature conditions and as a viscous liquid under chilled conditions. Preparation of ZUSDURI must be performed under aseptic conditions.

Storage Conditions and Handling

Before reconstitution, store ZUSDURI at room temperature, 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Avoid excessive heat over 40°C (104°F). Protect from light.

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).

ZUSDURI is a hazardous drug. Procedures for Proper Handling and Disposal of hazardous drugs should be followed.

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

Distributed by:

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OnGuard® is a registered trademark of Simplivia Healthcare, Ltd.

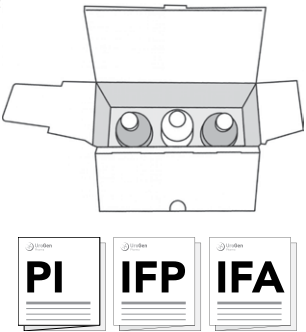
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ZUS-IFP-001

Supplies Needed

ZUSDURI available in a kit containing:

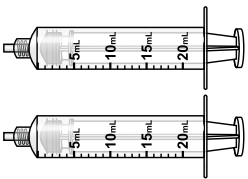
- Two vials of ZUSDURI, 40 mg per vial
- One vial of Sterile hydrogel, 60 mL
- One ZUSDURI admixture label
- ZUSDURI Prescribing Information (PI)
- ZUSDURI Instructions for Pharmacy (IFP)
- ZUSDURI Instructions for Administration (IFA)



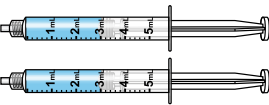
Pharmacy Supplies:
(Provided by your facility)

⚠ Do not substitute any of these components

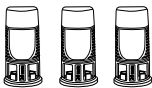
Two 20 mL Luer lock syringes



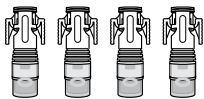
Two 5 mL Luer lock syringes filled with 3 mL sterile water



Three OnGuard®2 CSTD vial adaptors



Four OnGuard®2 CSTD syringe adaptors



Chilling Block or other means of chilling
(device design may vary)

Note: The day before the preparation, place the Chilling Block in the freezer at -20°C to -12°C (-4°F to 10.4°F). Refer to the Chilling Block Instructions for Use for more information.



Frequently Asked Questions

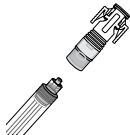
How do I connect the vial adaptor?

Place the vial adaptor over the vial and press down firmly. You will hear a snap which confirms successful attachment.



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.



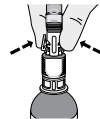
How do I connect the syringe adaptor to the vial adaptor?

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.



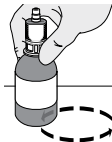
How do I disconnect the syringe adaptor from the vial adaptor?

Pinch the tabs on the syringe adaptor to separate it from the vial adaptor.



Do I have to keep the vials upright when mixing? If so, why?

Yes, the vials should be kept upright when mixing to ensure the contents are fully mixed at the bottom of the vial.



I am having difficulty working with the drug product. It seems to be solidifying.

If you are having difficulty pushing or withdrawing the solution, place the components back in the Chilling Block or other means of chilling until it liquifies.

Turn Over for More Information



Please [click here](#) for Full Prescribing Information.

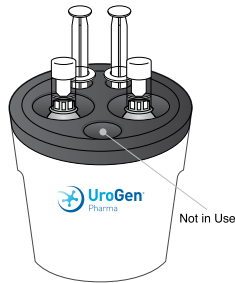
Steps to Prepare ZUSDURI Admixture

A FREEZE THE CHILLING BLOCK

1. The day before preparation, put the Chilling Block in the freezer at -20°C to -12°C (-4°F to 10.4°F).
Note: Please refer to the Chilling Block Instructions for Use for additional information.

B PREPARE SUPPLIES

1. Remove the Chilling Block from the freezer.
2. Disinfect the Chilling Block as per your pharmacy's policy. Allow it to air dry, and then place it inside the hood or isolator.
3. Connect vial adaptors to all three vials.
4. Connect syringe adaptors to **both** empty 20 mL syringes and **both** sterile water syringes.
5. Place one ZUSDURI vial, the sterile hydrogel vial, and **both** empty 20 mL syringes in the Chilling Block for approximately 20 minutes.
Note: The Chilling Block has five compartments, but only four are needed. The small vial compartment will not be used during this preparation.
6. Set the second ZUSDURI vial and both sterile water syringes aside for later use.



C RECONSTITUTE THE FIRST ZUSDURI VIAL

1. Slowly fill one chilled 20 mL syringe with 14 mL of sterile hydrogel.
2. Slowly fill the other chilled 20 mL syringe with 13 mL of sterile hydrogel.
3. Place both 20 mL syringes and the sterile hydrogel vial back in the Chilling Block.
4. Remove the chilled ZUSDURI vial from the Chilling Block.
5. Inject 3 mL of sterile water into the ZUSDURI vial.
6. Gently swirl the ZUSDURI vial upright at least 20 times.
Note: Do not invert or shake the vial.
7. Inject the chilled 14 mL and 13 mL syringes of sterile hydrogel into the ZUSDURI vial.
8. Place both empty 20 mL syringes back in the Chilling Block for later use.
9. Vigorously swirl the ZUSDURI vial upright for about 2 minutes.
Note: Do not invert or shake the vial.
10. Set the first ZUSDURI vial aside for later use.

D RECONSTITUTE THE SECOND ZUSDURI VIAL


1. Place the second ZUSDURI vial in the Chilling Block.
2. Slowly fill one chilled 20 mL syringe with 14 mL of sterile hydrogel.
3. Slowly fill the other chilled 20 mL syringe with 13 mL of sterile hydrogel.
4. Place both 20 mL syringes back in the Chilling Block.
5. Discard the empty sterile hydrogel vial.
6. Remove the chilled ZUSDURI Vial from the Chilling Block.
7. Inject 3 mL of sterile water into the ZUSDURI vial.
8. Gently swirl the ZUSDURI vial upright at least 20 times.
Note: Do not invert or shake the vial.
9. Inject the chilled 14 mL and 13 mL syringes of sterile hydrogel into the ZUSDURI vial.
10. Place both empty 20 mL syringes back in the Chilling Block for later use.
11. Vigorously swirl the ZUSDURI vial upright for about 2 minutes.
Note: Do not invert or shake the vial.

E COMBINE THE CONTENTS OF THE ZUSDURI ADMIXTURE VIALS

1. Slowly fill each chilled 20 mL syringe with 14 mL of admixture from the second ZUSDURI vial (for a total of 28 mL).
Note: If you are having difficulty withdrawing the admixture, place the components back in the Chilling Block until the admixture liquifies again.
2. Inject the two 14 mL admixture syringes into the first ZUSDURI vial.
3. You now have one vial that contains ZUSDURI admixture.

F DISPENSE RECONSTITUTED ZUSDURI

1. Write the “Discard after” date and time on the supplied admixture label and apply to the prepared ZUSDURI admixture vial. You may also substitute your pharmacy's label for dispensing the ZUSDURI admixture.
Note: The “Discard after” date and time is 7 days from the completion of the preparation. Store reconstituted ZUSDURI at 2°C to 8°C (36°F to 46°F) for up to 7 days. Alternatively, reconstituted ZUSDURI may be stored 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). Avoid excessive heat over 40°C (104°F). Protect from light.
2. Transport the following items to the treatment facility:
 - i. One reconstituted ZUSDURI vial.
 - ii. ZUSDURI Instructions for Administration (IFA).



IMPORTANT TO REMEMBER

- All components need to be kept cold during the preparation process by placing them in the Chilling Block or other means of chilling when they are not in use.
- If you are having difficulty pushing or withdrawing the solution at any time, place the components back in the Chilling Block or other means of chilling until the product liquifies again.



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

Please [click here](#) for Full Prescribing Information.

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