Zusduri™
(mitomycin) for intravesical solution

# What to Expect With **ZUSDURI Treatment**

## APPROVED USE FOR ZUSDURI

ZUSDURI (mitomycin) for intravesical solution is a prescription medicine used to treat adults with a type of cancer of the lining of the bladder called low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) after you have previously received bladder surgery to remove tumor and it did not work or is no longer working.

**You should not receive ZUSDURI if you** have a hole or tear (perforation) of your bladder or if you have had an allergic reaction to mitomycin or to any of the ingredients in ZUSDURI.

**Please see safety information and direction throughout and Patient Information.**

# What to Expect With ZUSDURI

## Before receiving ZUSDURI:

Tell your healthcare provider about all the medicines you take and all of your medical conditions, including if you:

- have kidney problems.
- are pregnant or plan to become pregnant. ZUSDURI can harm your unborn baby. You should not become pregnant during treatment with ZUSDURI. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with ZUSDURI.

**Females who are able to become pregnant:**

You should use effective birth control (contraception) during treatment with ZUSDURI and for 6 months after the last dose.

**Males being treated with ZUSDURI:**

You should use effective birth control (contraception) during treatment with ZUSDURI and for 3 months after the last dose.

- are breastfeeding or plan to breastfeed. It is not known if ZUSDURI passes into your breast milk. Do not breastfeed during treatment with ZUSDURI and for 1 week after the last dose.

## How ZUSDURI is given:


**Given once a week for 6 weeks.**
It is important that you receive all 6 doses of ZUSDURI according to your healthcare provider's instructions. If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

**Delivered directly in the bladder.**
ZUSDURI is delivered into your bladder through a urinary catheter. This is called intravesical instillation.

**The process to prepare and administer ZUSDURI usually takes less than 1 hour.**

Your healthcare provider may tell you to take additional medicines or change how you take your current medicines.

**Please see ZUSDURI Full Prescribing Information, including the Patient Information, for additional information.**

Zusduri™
(mitomycin) for intravesical solution

# What to Expect With ZUSDURI (cont)

## After receiving ZUSDURI:

ZUSDURI may cause your urine color to change to a violet or blue color.

Avoid contact between your skin and urine for at least 24 hours.

To urinate, **males and females** should sit on a toilet and flush the toilet several times after use.

After going to the bathroom, wash your hands, your inner thighs, and genital area well with soap and water.

Clothing that comes in contact with urine should be washed right away and washed separately from other clothing.

ZUSDURI slowly dissolves and will naturally pass out of your body when you urinate.

**With ZUSDURI, there is no need to hold your urine or to rotate positions to ensure the tumors are exposed to the medicine.**

**Please see ZUSDURI Full Prescribing Information, including the Patient Information, for additional information.**

Zusduri™
(mitomycin) for intravesical solution

# Possible Side Effects

Most side effects in the ZUSDURI clinical trial were mild-to-moderate, but serious side effects may occur.

**The most common side effects of ZUSDURI (occurring in ≥10% of patients) include:**

- Increased blood creatinine levels
- Increased blood potassium levels
- Trouble with urination*
- Decreased red blood cell counts
- Increase in certain blood liver tests
- Increased or decreased white blood cell counts
- Urinary tract infection
- Blood in your urine

Serious side effects occurred in 12% of patients (29 patients) who received ZUSDURI, including 2 patients with urinary retention (unable to fully empty the bladder) and 1 patient with urethral stenosis (narrowing of the tube that carries urine out of the body).

These are not all the side effects that can occur. Talk to your healthcare provider for medical advice on possible side effects.

You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. You may also report side effects to UroGen Pharma at 1-855-987-6436.

*Includes pain, discomfort, or a burning sensation during urination, as well as urinary frequency (urinating more often than usual), incontinence (loss of bladder control), retention, urethral stenosis, and urgency (a sudden, strong need to urinate).

Visit **ZUSDURI.com** for more information

**Please see ZUSDURI Full Prescribing Information, including the Patient Information, for additional information.**

Zusduri™
(mitomycin) for intravesical solution

# My ZUSDURI Treatment Log

To get the most out of your treatment, it is important to take all scheduled doses and attend all follow-up appointments. Use this log to keep track of your treatment schedule, note how you're feeling, and write down any questions or topics you'd like to discuss at your next doctor's visit:

## My appointments

| | | |
|---|---|---|
| TREATMENT **1** | Date: _____<br>Time: _____ | Notes: _____ |
| TREATMENT **2** | Date: _____<br>Time: _____ | Notes: _____ |
| TREATMENT **3** | Date: _____<br>Time: _____ | Notes: _____ |
| TREATMENT **4** | Date: _____<br>Time: _____ | Notes: _____ |
| TREATMENT **5** | Date: _____<br>Time: _____ | Notes: _____ |
| TREATMENT **6** | Date: _____<br>Time: _____ | Notes: _____ |

**Follow-up appointments:** _____

**Please see ZUSDURI Full Prescribing Information, including the Patient Information, for additional information.**

Zusduri (mitomycin) for intravesical solution

## Notes & Topics to Discuss:

Please see ZUSDURI Full Prescribing Information, including the Patient Information, for additional information.

Zusduri™
(mitomycin) for intravesical solution

# Patient Information

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

## What is ZUSDURI?

ZUSDURI is a prescription medicine used to treat adults with a type of cancer of the lining of the bladder called low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC) after you have previously received bladder surgery to remove tumor and it did not work or is no longer working.

It is not known if ZUSDURI is safe and effective for use in children.

## Who should not receive ZUSDURI?

**Do not receive ZUSDURI if you:**

- have a hole or tear (perforation) of your bladder,
- have had an allergic reaction to mitomycin or to any of the ingredients in ZUSDURI. See the end of this Patient Information for a complete list of the ingredients in ZUSDURI.

**Before receiving ZUSDURI, tell your healthcare provider about all of your medical conditions, including if you:**

- have kidney problems.
- are pregnant or plan to become pregnant. ZUSDURI can harm your unborn baby. You should not become pregnant during treatment with ZUSDURI. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with ZUSDURI.

**Females who are able to become pregnant:**

- Your healthcare provider will check to see if you are pregnant before starting treatment with ZUSDURI.
- You should use effective birth control (contraception) during treatment with ZUSDURI and for 6 months after the last dose.
- Talk to your healthcare provider if you have questions about birth control options that are right for you.

**Males being treated with ZUSDURI:**

- If you have a female partner who is able to become pregnant, you should use effective birth control (contraception) during treatment with ZUSDURI and for 3 months after the last dose.

- are breastfeeding or plan to breastfeed. It is not known if ZUSDURI passes into your breast milk. Do not breastfeed during treatment with ZUSDURI and for 1 week after the last dose.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

## How will I receive ZUSDURI?

- ZUSDURI will be given to you by your healthcare provider.
- You will receive ZUSDURI 1 time a week for 6 weeks into your bladder through a tube called a urinary catheter. It is important that you receive all 6 doses of ZUSDURI according to your healthcare provider's instructions.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

**Please see ZUSDURI Full Prescribing Information, including the Patient Information, for additional information.**

Zusduri™
(mitomycin) for intravesical solution

- During treatment with ZUSDURI, your healthcare provider may tell you to take additional medicines or change how you take your current medicines. Ask your healthcare provider if you have any questions.

**After receiving ZUSDURI:**

- ZUSDURI may cause your urine color to change to a violet to blue color.
- Avoid contact between your skin and urine for at least 24 hours.
- To urinate, **males and females should sit** on a toilet and flush the toilet several times after you use it.
- After going to the bathroom, wash your hands, your inner thighs, and genital area well with soap and water.
- Clothing that comes in contact with urine should be washed right away and washed separately from other clothing.

**What are the possible side effects of ZUSDURI?**

**The most common side effects of ZUSDURI include:**

- increased blood creatinine levels
- increased blood potassium levels
- trouble with urination
- decreased red blood cell counts
- increase in certain blood liver tests
- increased or decreased white blood cell counts
- urinary tract infection
- blood in your urine

Call your doctor for medical advice about possible side effects. You may report side effects to FDA at 1-800-FDA-1088. You can also report side effects to UroGen Pharma at 1-855-987-6436.

**General information about ZUSDURI.**

Medicines are sometimes prescribed for purposes other than those listed in this Patient Information. You can ask your pharmacist or healthcare provider for information about ZUSDURI that is written for healthcare professionals.

**What are the ingredients of ZUSDURI?**

**Active ingredient:** mitomycin

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

Distributed by: UroGen Pharma, Inc., Princeton, NJ 08540



For more information, go to www.ZUSDURI.com or call 1-855-987-6436.

This Patient Information has been approved by the U.S. Food and Drug Administration.
Issued: 06/2025

**Please see ZUSDURI Full Prescribing Information, including the Patient Information, for additional information.**



Zusduri (mitomycin) for intravesical solution