

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 leaflet 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.
- 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:

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| • increased blood creatinine levels | • increase in certain blood liver tests |
| • increased blood potassium levels | • increased or decreased white blood cell counts |
| • trouble with urination | • urinary tract infection |
| • decreased red blood cell counts | • 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 leaflet. 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

ZUSDURI™ is a trademark and UroGen® is a registered trademark of UroGen Pharma, Ltd.

U.S. Patent Nos. 9,040,074, 9,950,069 and 10,039,832

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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