

Moving forward with **ZUSDURI**

The 1st and only FDA-approved, non-surgical treatment for recurrent LG-IR-NMIBC



Recurrent means the cancer came back.

FDA=Food and Drug Administration; LG-IR-NMIBC=low-grade intermediate-risk non-muscle invasive bladder cancer. *Compensated for his time.

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 intermediaterisk 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.

IMPORTANT SAFETY INFORMATION

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 Important Safety Information on pages 8 and 9 and <u>click here</u> for Full Prescribing Information, including the <u>Patient Information</u>.

Understanding LG-IR-NMIBC

Non-muscle invasive bladder cancer (NMIBC) accounts for ~75% of all bladder cancers. NMIBC is confined to the inner lining of the bladder. The cancer has not reached the bladder's muscle wall.

NMIBC is classified by *grade*, *stage*, and *risk level* to help doctors choose the appropriate treatment.

One type of NMIBC is called LG-IR-NMIBC:

- LG (low-grade) means the tumor cells appear near-normal and are slow growing
- IR (intermediate-risk) means there is a medium risk of cancer coming back or spreading
- LG-IR-NMIBC is defined by having 1 or 2 of the following*:
 - -Low-grade, single large Ta tumor[†] (>3 cm)
 - -Low-grade, multiple Ta tumors
 - -Low-grade Ta tumor(s) that come back within 1 year after treatment

The standard treatment for LG-IR-NMIBC is <u>TURBT</u> (a surgical procedure to remove the tumors). This is sometimes followed by intravesical induction therapy with liquid-form chemotherapy or a type of immunotherapy called BCG. This may be followed by more doses as <u>maintenance</u> therapy for up to one year. Despite current treatments, LG-IR-NMIBC will often recur (come back). Upon recurrence, patients will often undergo repeat surgery.

Now, there is a different approach to treating recurrent LG-IR-NMIBC

BCG=bacillus Calmette-Guérin; TURBT=transurethral resection of bladder tumor.



^{*}As defined in the ZUSDURI clinical trial. †Ta tumors grow toward the hollow center of the bladder and are considered the earliest stage of bladder cancer.

How does ZUSDURI work to fight your cancer?

Innovative gel technology



- Administered as a liquid, ZUSDURI (Zuss-dur-ee) changes into a gel at body temperature and releases mitomycin (MY-toh-MY-sin) in the bladder. Mitomycin has been used extensively to treat certain cancers for many years
- Works in your bladder, where it's needed. There is no need to hold your urine or rotate positions to ensure the tumors are exposed to the medicine
- After receiving ZUSDURI, avoid contact between your skin and urine for at least 24 hours

Delivered directly in the bladder



- Administered in the doctor's office or an outpatient clinic.
 No need for surgery or general anesthesia
- Medicine is given through a catheter inserted through the urethra into the bladder. This is called intravesical therapy or IVT
- The amount of ZUSDURI in the blood is less than 1% of what would be expected with mitomycin when given intravenously (through a vein)

IMPORTANT SAFETY INFORMATION

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.

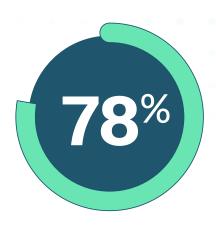
Clothing that comes in contact with urine should be washed right away and washed separately from other clothing.



ZUSDURI: powerful results that last

In the ZUSDURI clinical trial, 223 patients with recurrent LG-IR-NMIBC received ZUSDURI once a week for 6 weeks.

The results of the ZUSDURI trial showed:



of patients

had no detectable tumor at 3 months after treatment with ZUSDURI

(No detectable tumor is also called a complete response or CR)



of patients who had no detectable tumor at 3 months were

still tumor-free 12 months later

IMPORTANT SAFETY INFORMATION

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.



ZUSDURI side effects

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

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

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

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**.

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: 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.

Tell your healthcare provider if you 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.

See additional IMPORTANT SAFETY INFORMATION throughout.



What to expect when receiving treatment with ZUSDURI

Start by talking with your healthcare provider

- ZUSDURI is typically given in a doctor's office or an outpatient clinic. You and your healthcare provider should talk about your particular case and what to expect
- Follow all of the instructions from your healthcare provider prior to and after treatment

During treatment



6 doses in total

Given once a week for 6 weeks



Delivered directly in the bladder

- Your healthcare provider will give you ZUSDURI through a thin, flexible tube called a urinary catheter. The catheter will be inserted through your urethra and into your bladder. This method of delivering medicine is called intravesical therapy (IVT)
- The process generally includes ~20 minutes to prepare ZUSDURI for administration, ~10 minutes to administer, and ~15 minutes before the catheter is removed



• With ZUSDURI, there's no need to hold in your urine or rotate positions to ensure the tumors are exposed to the medicine



There's no need for general anesthesia or surgery and patients go home the same day

During treatment with ZUSDURI, your healthcare provider may tell you to take additional medicines or change how you take your current medicines.



What to expect when receiving treatment with ZUSDURI (cont'd)

After treatment

- ZUSDURI slowly becomes liquid and is naturally flushed out of your body in your urine
- · ZUSDURI may cause your urine color to change to a violet to blue color

These precautions are recommended:

- 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.

It's important that you receive all 6 doses of ZUSDURI.

If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment



Indication and Important Safety Information

APPROVED USE FOR ZUSDURI

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IMPORTANT SAFETY INFORMATION

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.

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: 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.



Important Safety Information (cont'd)

How will I receive ZUSDURI?

- You will receive your ZUSDURI dose from your healthcare provider 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.

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.

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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch** or call 1-800-FDA-1088. You may also report side effects to UroGen Pharma at 1-855-987-6436.



Patient support programs

We understand that navigating treatment costs can feel overwhelming. For eligible patients, there may be a program that can help you with affordability, access, and to determine your insurance coverage. These are available through your doctor's office.



Insurance coverage determination

We will work with your doctor's office to check on what the insurance company will reimburse and what your copay may be.



Commercial copay program

You may qualify for the UroGen Support™ Copay Program. If you are eligible, you will pay as little as \$50 for each dose with a maximum benefit of \$14,000/year. Additional terms and conditions apply.



Independent charitable foundation support

If you have Medicare or Medicaid, charitable foundations may help pay for your treatment. Ask your doctor about which foundations are available.



Patient assistance program

If you don't have insurance, you may qualify for the UroGen Support™ Patient Assistance Program. If you qualify, this program will cover the cost of ZUSDURI.

For additional resources and support, visit **ZUSDURI.com**



Take care of yourself: prioritize your well-being

Self-care can be your greatest ally in your fight against cancer

Nourish your body

Eat a balanced diet rich in fruits, vegetables, and whole grains. Stay hydrated, get enough rest, and stay active however you can.

Keeping up with follow-up appointments is also key.

Find recipes and tips that support improved bladder health at https://bcan.org/recipes-for-bladder-cancer-patients.

Support your mental well-being

Manage stress with relaxation techniques like journaling, meditation, or deep breathing. Stay connected with supportive people, explore creative outlets, and find what brings you peace.

Find coping and relaxation tips at cancercare.org/meditation-exercises.



Quit smoking

Research shows that smoking can increase the chances of getting cancer at the same site or another site. If you need help quitting, resources are available. Visit **smokefree.gov** for support, tools, and expert advice to help you stop smoking for good.

Taking care of your whole self will empower you throughout your journey



^{*}Compensated for his time.

My ZUSDURI treatment journal

Use this chart to track your treatment schedule.

My appointments

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My ZUSDURI treatment journal (cont'd)

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My ZUSDURI treatment journal (cont'd)

Keep the conversation open. For any concerns, your care team is just a call away.

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The 1st and only FDA-approved, non-surgical treatment for recurrent LG-IR-NMIBC

Powerful, lasting results

In a clinical trial, 78% of patients had no detectable tumor at 3 months and 79% of these patients remained tumor-free 12 months later

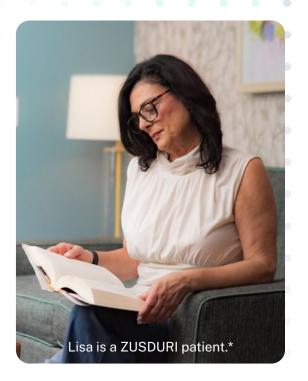
6 doses in total

Delivered directly in the bladder, where it's needed

Given in the doctor's office or clinic

No need for general anesthesia or surgery

Patient support programs for eligible patients available through your doctor's office



Visit **ZUSDURI.com** for more information and to sign up for updates

*Compensated for her time.

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