Zusduri™
(mitomycin) for intravesical solution

Communications Toolkit

Resources for Healthcare Providers

Indications and Usage

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

Contraindications

ZUSDURI is contraindicated in patients with perforation of the bladder or in patients with prior hypersensitivity reactions to mitomycin or any component of the product.

UroGen® Pharma

Welcome

This Communications Toolkit offers resources to help, should you choose to share information about ZUSDURI™ (mitomycin) for intravesical solution at your facility. It includes examples designed for educating local urologists, and for sharing these resources with healthcare providers and patients within your facility.

If you have any questions about the Communications Tool Kit, please contact your local ZUSDURI representative.

ZUSDURI Communications Toolkit

- Toolkit Overview
- ZUSDURI Key Points
- Resources for Healthcare Providers
- Public Relations Materials
- ZUSDURI Important Safety Information
- ZUSDURI Full Prescribing Information

ZUSDURI Key Points

- ZUSDURI is the first and only FDA-approved medication for adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).
- ZUSDURI is delivered where it's needed — releasing mitomycin directly in the bladder.
- ZUSDURI uses UroGen's advanced RTGel® technology, a sustained release, hydrogel-based formulation, to enable prolonged exposure of bladder tissue to mitomycin, with a median dwell time of 5 hours and reports of up to 24 hours.
  - Based on patient-reported visibility of gel in urine post-treatment. Advise patients for at least 24 hours post-instillation to avoid urine contact with skin.
- ZUSDURI is designed for potent tumor ablation. It is delivered using a urinary catheter in-office or in an outpatient setting by a trained healthcare professional.
- The efficacy of ZUSDURI was evaluated in the phase 3 ENVISION, single-arm, multicenter clinical trial in 240 adults with recurrent LG-IR-NMIBC, of whom 223 were evaluable for response. The clinical trial demonstrated 78% (95% CI: 72, 83) of ZUSDURI patients achieved complete response (CR) at 3 months. 79% of responders maintained CR 12 months later.
- The safety of ZUSDURI was evaluated in the phase 3 ENVISION single-arm, multicenter clinical trial in 240 patients with recurrent LG-IR-NMIBC. ZUSDURI has a manageable safety profile with mainly mild to moderate lower urinary tract symptoms.
  - Serious adverse reactions occurred in 12% of patients who received ZUSDURI, including urinary retention (0.8%) and urethral stenosis (0.4%).
  - The most common (≥ 10%) adverse reactions, including laboratory abnormalities, that occurred in patients were increased creatinine, increased potassium, dysuria, decreased hemoglobin, increased aspartate aminotransferase, increased alanine aminotransferase, increased eosinophils, decreased lymphocytes, urinary tract infection, decreased neutrophils, and hematuria.

For more information on ZUSDURI, please see the Full Important Safety Information below and refer to the Full Prescribing information, which is available as a download here.

Resources For Healthcare Providers

The following resources are available to inform and educate local HCPs and community members about ZUSDURI.

ZUSDURI Fact Sheet

The ZUSDURI Fact Sheet offers an overview of ZUSDURI, its innovative technology, RTGel®, and key data from the Phase 3 ENVISION trial. It's ready for distribution as-is but can also be placed on your institution's letterhead.

Download the ZUSDURI Factsheet

ZUSDURI Key Messages and Frequently Asked Questions

The purpose of this document is to provide your facility with accurate information that you may use to create communications or respond to potential media inquiries regarding ZUSDURI. Please note this document is for internal use only and should not be distributed externally.

Download the ZUSDURI Key Messages and Frequently Asked Questions

ZUSDURI Patient Referral Tracker

Treating complex diseases often requires a team approach. Some urology practices may not be equipped to administer ZUSDURI to adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer, making referral a viable option. This tool can assist with the referral process and ensure continuity of care for patients.

Download the ZUSDURI Patient Referral Tracker

Communications Examples

You have an exciting story to tell as a leading center for urologic care and one of the facilities in your community to offer ZUSDURI for the medication of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). The following resources may be used to help create your own communications, educate the healthcare community and local media, and/or to respond to potential media inquiries. Please work with your internal communications team for review and approval of this content as needed.

Communication of Product Availability

The Communication of Product Availability is an example of how you can announce the availability of ZUSDURI at your institution and your expertise.

Download the Communication of Product Availability

Social Media Examples

The Social Media Guidance document offers considerations for sharing information on your social media platforms. Please get your facility's approval before sharing, and research relevant regulations to you and your organization prior to posting.

Download Social Media Guidance

Understanding NMIBC: What You Need to Know

This disease state backgrounder offers an overview of LG-IR-NMIBC, including epidemiology, disease state information, unmet needs for this patient population, and current treatments. It's ready for distribution as-is.

Download Understanding NMIBC

Institution Internal Communications Email Example

The Institution Internal Communications Email is an example of how you can announce the availability of ZUSDURI at your institution.

Download Institution Internal Communications Email Example

ZUSDURI Healthcare Provider and Patient Testimonials

Real-life experiences can effectively educate local urologists about ZUSDURI. Consider using testimonials from staff and patients on your website and other media. Consult with your legal department for required disclosures and consent.

ZUSDURI™ (mitomycin) for Intravesical Use

IMPORTANT SAFETY INFORMATION

Contraindications

ZUSDURI is contraindicated in patients with perforation of the bladder or in patients with prior hypersensitivity reactions to mitomycin or any component of the product.

Warnings and Precautions

Risks in Patients with Perforated Bladder

ZUSDURI may lead to systemic exposure to mitomycin and severe adverse reactions if administered to patients with a perforated bladder or to those in whom the integrity of the bladder mucosa has been compromised. Evaluate the bladder before the intravesical instillation of ZUSDURI and do not administer to patients with a perforated bladder or mucosal compromise until bladder integrity has been restored.

Embryo-Fetal Toxicity

Based on findings in animals and mechanism of action, ZUSDURI can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of mitomycin resulted in teratogenicity. Advise females of reproductive potential to use effective contraception during treatment with ZUSDURI and for 6 months following the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ZUSDURI and for 3 months following the last dose.

Adverse Reactions

Common Adverse Reactions

The most common (≥10%) adverse reactions, including laboratory abnormalities, that occurred in patients treated with ZUSDURI were increased creatinine, increased potassium, dysuria, decreased hemoglobin, increased aspartate aminotransferase, increased alanine aminotransferase, increased eosinophils, decreased lymphocytes, urinary tract infection, decreased neutrophils, and hematuria.

Additional Adverse Reactions Information

Clinically relevant adverse reactions occurring in <10% of patients who received ZUSDURI included

increased urinary frequency, fatigue, urinary incontinence, urinary retention, urethral stenosis, genital pain, urinary urgency, genital edema, genital pruritus, genital rash, urethritis, acute kidney injury, balanoposthitis, and nocturia.

Use in Specific Populations

Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with ZUSDURI and for 1 week following the last dose.

Preparation and Administration Information

ZUSDURI is to be administered by intravesical instillation only. Do not administer ZUSDURI by pyelocalyceal instillation or by any other route.

ZUSDURI must be prepared and administered by a healthcare provider. To ensure proper dosing, it is important to follow the preparation instructions found in the ZUSDURI Instructions for Pharmacy and administration instructions found in the ZUSDURI Instructions for Administration.

ZUSDURI may discolor urine to a violet to blue color following the instillation procedure. Advise patients for at least 24 hours post-instillation to avoid urine contact with skin, to void urine sitting on a toilet, and to flush the toilet several times after use. Advise patients to wash hands, perineum or glans with soap and water after each instillation procedure.

ZUSDURI is a hazardous drug. Follow applicable special handling and disposal procedures.

Please see accompanying Full Prescribing Information, Instructions for Pharmacy and Instructions for Administration.