

Patient Information
JELMYTO® (jel-MYE-toe)
(mitomycin)
for pyelocalyceal solution

What is JELMYTO?

JELMYTO is a prescription medicine used to treat adults with a type of cancer of the lining of the upper urinary tract including the kidney called low-grade Upper Tract Urothelial Cancer (LG-UTUC).

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

Who should not receive JELMYTO?

Do not receive JELMYTO if you have a hole or tear (perforation) of your bladder or upper urinary tract.

Before receiving JELMYTO, tell your healthcare provider about all your medical conditions, including if you:

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

Females who are able to become pregnant:

- Your healthcare provider will check to see if you are pregnant before starting treatment with JELMYTO.
- You should use effective birth control (contraception) during treatment with JELMYTO 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 JELMYTO:

- If you have a female partner who is able to become pregnant, you should use effective birth control (contraception) during treatment with JELMYTO and for 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if JELMYTO passes into your breast milk. Do not breastfeed during treatment with JELMYTO 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.

Especially tell your healthcare provider if you take water pills (diuretic).

How will I receive JELMYTO?

- Your healthcare provider will tell you to take a medicine called sodium bicarbonate before each JELMYTO treatment. Your healthcare provider will provide instructions about how and when to take sodium bicarbonate.
- JELMYTO will be given to you by your healthcare provider.
- You will receive JELMYTO 1 time a week for 6 weeks. It is important that you receive all 6 doses of JELMYTO according to your healthcare provider's instructions. Your healthcare provider may recommend up to an additional 11 monthly doses.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.
- JELMYTO is given to your kidney through a tube called a catheter.
- During treatment with JELMYTO, 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 JELMYTO:

- JELMYTO may cause your urine color to change to a violet to blue color.
- Avoid contact between your skin and urine for at least 6 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 JELMYTO?

JELMYTO may cause serious side effects, including:

- **Swelling and narrowing of the tube that carries urine from the kidney to the bladder (ureteric obstruction).** If you develop swelling and narrowing, and to protect your kidney from damage, your healthcare provider may recommend the placement of a small plastic tube (stent) in the ureter to help the kidney drain. Tell your healthcare provider right away if you develop side pain or fever during treatment with JELMYTO.
- **Bone marrow problems.** JELMYTO can affect your bone marrow and can cause a decrease in your white blood cell, red blood cell, and platelet counts. Your healthcare provider will do blood tests prior to each treatment to check your blood cell counts during treatment with JELMYTO. Your healthcare provider may need to temporarily or permanently stop JELMYTO if you develop bone marrow problems during treatment with JELMYTO.

The most common side effects of JELMYTO include:

- urinary tract infection
- blood in your urine
- side pain
- nausea
- trouble with urination
- kidney problems
- vomiting
- tiredness
- stomach (abdomen) pain

Call your doctor for medical advice about 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 JELMYTO.

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 JELMYTO that is written for healthcare professionals.

What are the ingredients of JELMYTO?

Active ingredient: mitomycin

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

Distributed by:

UroGen Pharma, Inc.

Princeton, NJ 08540

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

This Patient Information has been approved by the U.S. Food and Drug Administration.

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