

What to expect after treatment with JELMYTO

In order to make the most of your treatment experience, there are some important things to keep in mind once you start receiving JELMYTO.

Taking precautions when you urinate

JELMYTO may cause your urine to turn a violet to blue color after treatment, but your urine flow should otherwise be normal. Because JELMYTO leaves your body when you urinate, it's important to be careful after treatment. Please follow these instructions when you're at home:

- ✓ Avoid contact with urine for at least 6 hours after the treatment
- ✓ Wash your hands, inner thighs, and groin with soap and water after urination
- ✓ Male and female patients both should sit on a toilet and flush the toilet several times after use
- ✓ Wash clothing right away and by itself (not with other clothes) if any urine gets on them

What are the possible side effects of JELMYTO?

When taking JELMYTO, it's possible to experience some side effects. You may not be familiar with all of these side effects, so it's important to pay attention to how you are feeling and talk to your doctor about any changes that you notice.

JELMYTO may cause serious side effects, including

Swelling of the ureter. Ureteric obstruction is a swelling and narrowing of the tube that carries urine from your kidneys to the bladder (your ureter). Tell your healthcare provider immediately if you have side pain or fever.

Ureteric obstruction can be treated. Your doctor may recommend placing a plastic stent (called a ureteral stent) in your ureter to help your kidneys drain. This will help to prevent damage to your kidney.

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. Because of this, your healthcare provider will do blood tests before each treatment to check your blood cell count. If you develop a bone marrow problem, you may need to temporarily or permanently stop taking JELMYTO.

Please see next page for most common side effects.

Please [click here](#) for JELMYTO Full Prescribing Information, and see the accompanying Patient Information, for additional information.

The most common side effects of JELMYTO include

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

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

What to know if you are sexually active:



For women:

- Do not become pregnant during treatment with JELMYTO. If you become pregnant, contact your doctor immediately
- Do not breastfeed during treatment with JELMYTO



For men:

- If you have a female partner who may become pregnant, use effective birth control. It should be used during treatment with JELMYTO and for 3 months after the last dose

It's important to complete all 6 doses of JELMYTO. If you miss an appointment, call your doctor right away to reschedule.

NOTES:

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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 | • kidney problems |
| • blood in your urine | • vomiting |
| • side pain | • tiredness |
| • nausea | • stomach (abdomen) pain |
| • trouble with urination | |

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

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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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