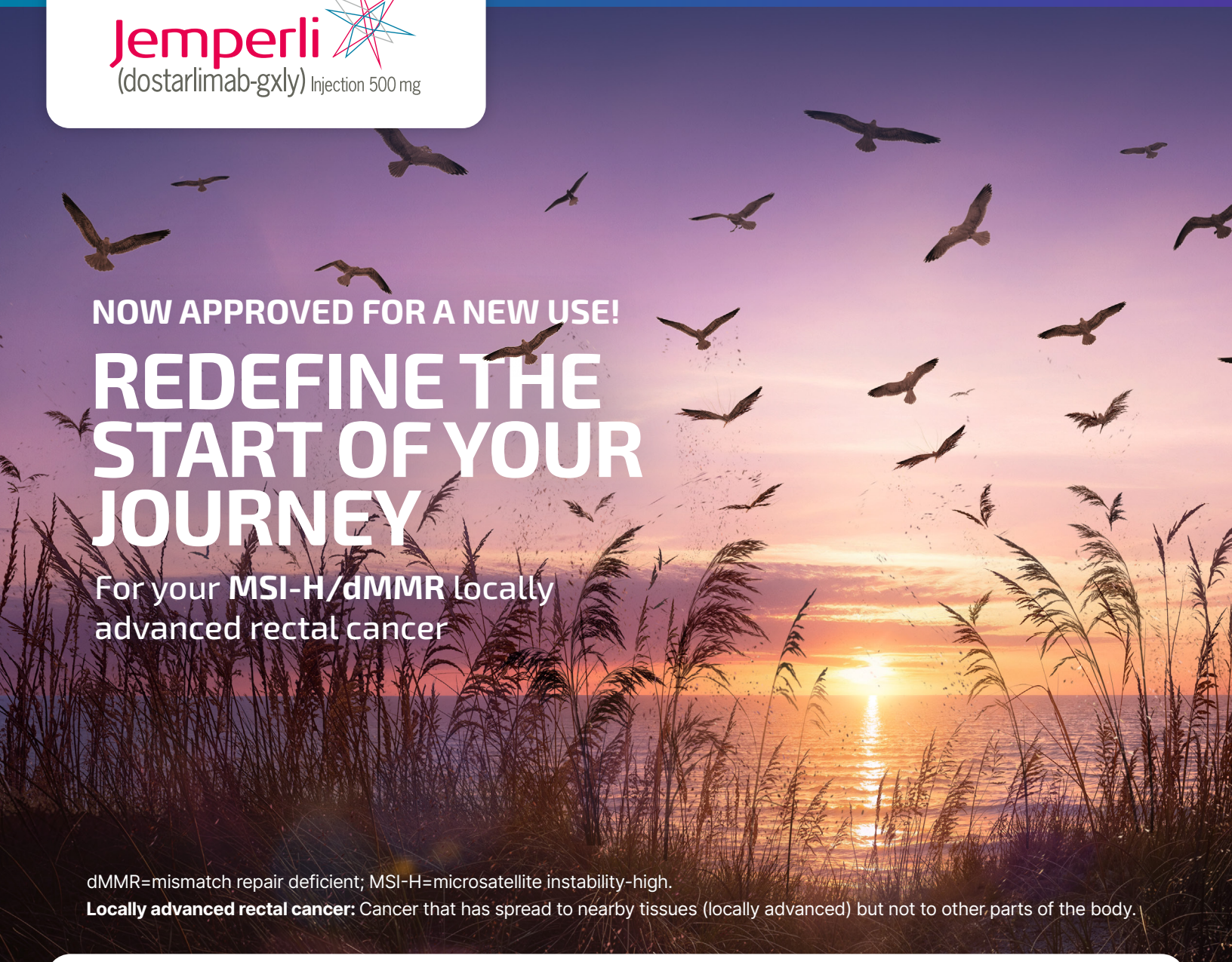
Jemperli
(dostarlimab-gxly) Injection 500 mg



NOW APPROVED FOR A NEW USE!

REDEFINE THE START OF YOUR JOURNEY

For your **MSI-H/dMMR** locally advanced rectal cancer

dMMR=mismatch repair deficient; MSI-H=microsatellite instability-high.
Locally advanced rectal cancer: Cancer that has spread to nearby tissues (locally advanced) but not to other parts of the body.

Approved Use

JEMPERLI is a prescription medicine used to treat adults with a kind of cancer called rectal cancer. JEMPERLI may be used alone to treat rectal cancer that:

- is Stage II or III and has spread to nearby tissues (locally advanced) but not to other parts of the body, **and**
- is shown by a laboratory test to be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).
- This use is approved based on clinical complete response (defined as no signs of cancer) maintained for 12 months. The risk of the cancer returning over time is unknown, and researchers will continue to gather more information. Studies are ongoing to confirm the clinical benefit of JEMPERLI for this use.

It is not known if JEMPERLI is safe and effective in children.

Important Safety Information

JEMPERLI is a medicine that may treat certain cancers by working with your immune system. JEMPERLI can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide, also available at JEMPERLI.com.

JEMPERLI treats MSI-H/dMMR locally advanced rectal cancer and may help you avoid surgery, radiation, and/or chemotherapy

Most people diagnosed with rectal cancer are treated with multiple therapies like chemotherapy, radiation, and surgery. While these treatments can be effective at treating cancer, they can also create lasting physical issues. JEMPERLI offers another approach to treatment, but can also cause potential side effects, which can be found on page 8.

Your locally advanced rectal cancer has a characteristic or a biomarker called MSI-H or dMMR, which accounts for up to 10% of cases.

dMMR or mismatch repair deficient: Refers to cancers with a defective mismatch repair (MMR) system (a system that corrects mistakes that occur in genes during normal cell growth).

MSI-H or microsatellite instability-high: Describes unstable genes in some tumors that may occur because the MMR system is not repairing mistakes properly.

National cancer treatment guidelines recommend that **anyone diagnosed with rectal cancer should be tested as soon as possible for MMR/microsatellite instability (MSI) biomarkers.** Getting this information early helps healthcare teams provide patients with the most appropriate treatment options for them.

Important Safety Information (cont'd)

Call or see your healthcare provider (HCP) right away if you develop any new or worsening signs or symptoms, including:

Lung problems. Signs and symptoms may include cough, shortness of breath, or chest pain.

Intestinal problems. Signs and symptoms may include diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; or severe stomach-area (abdomen) pain or tenderness.

Liver problems. Signs and symptoms may include yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (tea colored), or bleeding or bruising more easily than usual.

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What does that mean for me?

During normal cell growth, the MMR system corrects mistakes that occur in genes. If the MMR system is not working properly, this is known as MSI-H or dMMR.

Rectal tumors with MSI-H/dMMR biomarkers may be less responsive to standard chemotherapy. People with MSI-H/dMMR locally advanced rectal cancer might benefit from an immunotherapy like JEMPERLI.

Immunotherapy: A treatment that is not chemotherapy or radiation, but is designed to work with the body to help fight cancer.

MSI-H/dMMR status may be associated with Lynch syndrome, an inherited condition that increases the risk of developing rectal cancer.

JEMPERLI is an immunotherapy that harnesses the immune system to attack cancer cells.

Tumors with MSI-H/dMMR may be more likely to respond to an immunotherapy like JEMPERLI. Changes in genes provide the immune system with more clues to find and attack cancer cells, improving its ability to fight the cancer.

Important Safety Information (cont'd)

Call or see your healthcare provider (HCP) right away if you develop any new or worsening signs or symptoms, including (cont'd):

Hormone gland problems. Signs and symptoms may include headaches that will not go away or unusual headaches, eye sensitivity to light, eye problems, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, feeling more hungry or thirsty than usual, urinating more often than usual, hair loss, feeling cold, constipation, your voice gets deeper, dizziness or fainting, changes in mood or behavior such as decreased sex drive, irritability, or forgetfulness.

Kidney problems. Signs and symptoms may include change in the amount or color of your urine, blood in your urine, swelling in your ankles, or loss of appetite.

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How JEMPERLI was studied in people like you

JEMPERLI is the only immunotherapy that's FDA-approved to treat MSI-H/dMMR locally advanced rectal cancer. It was studied in two separate clinical trials to measure the potential benefits and risks to patients.

The first clinical trial was conducted by the internationally recognized Memorial Sloan Kettering Cancer Center (MSKCC). In the MSKCC 19-288 trial, 50 study participants who had not yet been treated for MSI-H/dMMR locally advanced rectal cancer received JEMPERLI alone. The results of this trial led to a second, larger trial called AZUR-1, sponsored by GSK, the manufacturer of JEMPERLI.

Based on the MSKCC trial results, JEMPERLI received Breakthrough Therapy designation, a status granted by the FDA that accelerates the development and review of medicines for serious conditions when early clinical results suggest they may offer improvement over current options.

The AZUR-1 clinical trial included 154 people with the same type of rectal cancer and built upon the results of the MSKCC trial.

Study participants received

JEMPERLI 500 mg intravenously

every 3 weeks for 9 cycles, or over the course of about 6 months.

- After treatment with JEMPERLI, doctors looked for signs of cancer through physical exams, a procedure called an endoscopy, and imaging tests. If they found no signs of cancer after treatment, this was called a clinical complete response (cCR)
- The main goal of the AZUR-1 clinical trial was to see how many people had a cCR that was maintained for at least 12 months (cCR12), as confirmed by a team of independent experts
- If the cancer did not disappear completely after JEMPERLI treatment, study participants could go on to receive other standard treatments (possibly including a combination of chemotherapy, radiation, and/or surgery)

Important Safety Information (cont'd)

Call or see your healthcare provider (HCP) right away if you develop any new or worsening signs or symptoms, including (cont'd):

Skin problems. Signs and symptoms may include rash; itching; skin blistering or peeling; swollen lymph nodes; painful sores or ulcers in your mouth or in your nose, throat, or genital area; fever or flu-like symptoms.

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With JEMPERLI, many patients with MSI-H/dMMR locally advanced rectal cancer achieved cCR12 without the need for chemotherapy, radiation, or surgery

The main goal of the study was to measure **cCR12 or clinical complete response maintained for at least 12 months.** This means doctors could not find signs of cancer after treatment in endoscopy or imaging tests over 12 months as confirmed by an independent team of experts, also known as an independent central review. The results were also reviewed by the researchers who ran the study (study investigators).

In the study, 154 patients received JEMPERLI. To measure cCR12, 116 participants were evaluated by independent central review and 144 were evaluated by study investigators to see if they were able to maintain a cCR for at least 12 months following treatment.

cCR12 - CLINICAL COMPLETE RESPONSE OVER 12 MONTHS

Per Independent Central Review (ICR)

47% ➡ **54 OUT OF 116**

Per Investigator Assessment

68% ➡ **98 OUT OF 144**

participants had their tumors completely disappear* and **stay gone for at least 1 year without chemotherapy, radiation, or surgery.**

ICR or independent central review includes independent medical experts who review results based on a guide.

Investigator assessment is performed by the doctors and healthcare team who are conducting the study.

*This does not always mean that the cancer has been cured.

Important Safety Information (cont'd)

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with JEMPERLI. Call or see your HCP right away for any new or worsening signs or symptoms. Signs and symptoms may include chest pain, irregular heartbeat, shortness of breath, swelling of ankles; persistent or severe muscle pain or weakness, muscle cramps; confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs; double vision, blurry vision, drooping eyelids, sensitivity to light, eye pain, changes in eyesight; low red blood cells, bruising.

Infusion reactions that can sometimes be severe or life-threatening. Signs and symptoms of infusion reactions may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feel like passing out, fever, back or neck pain.

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With JEMPERLI, most patients with MSI-H/dMMR locally advanced rectal cancer had their tumors disappear,* nearly disappear, or partially shrink

Another goal of the study was to measure **objective response rate (ORR)**, defined as the percentage of participants whose tumors completely disappeared* (clinical complete response or cCR), nearly disappeared (near-complete response or nCR), or partially shrank (partial response or PR) within a certain period of time after receiving JEMPERLI. The results were reviewed by independent central review and the study investigators.

ORR - OBJECTIVE RESPONSE RATE

Per Independent Central Review (ICR)

79% ➡ **121 OUT OF 154**

Per Investigator Assessment

82% ➡ **126 OUT OF 154**

participants had their **tumors completely disappear,* nearly disappear, or partially shrink.**

- **Clinical Complete Response (cCR):** 28% (43 out of 154) of participants per ICR, and 66% (102 out of 154) of participants per investigator
- **Near-Complete Response (nCR):** 29% (44 out of 154) of participants per ICR, and 6% (9 out of 154) of participants per investigator
- **Partial Response (PR):** 22% (34 out of 154) of participants per ICR, and 10% (15 out of 154) of participants per investigator

*This does not always mean that the cancer has been cured.

Important Safety Information (cont'd)

Rejection of a transplanted organ or tissue. Your HCP should tell you what signs and symptoms you should report and monitor you, depending on the type of organ or tissue transplant that you have had.

Complications, including graft-versus-host-disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with JEMPERLI. Your HCP will monitor you for these complications.

Getting medical treatment right away may help keep these problems from becoming more serious. Your HCP will check you for these problems during treatment with JEMPERLI and may treat you with corticosteroid or hormone replacement medicines. If you have severe side effects, your HCP may also need to delay or completely stop treatment with JEMPERLI.

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An earlier trial was conducted at the internationally recognized Memorial Sloan Kettering Cancer Center (MSKCC)

The MSKCC trial measured:

- **Overall response rate:** the percentage of participants whose tumors completely disappeared* (cCR) or nearly disappeared (nCR) after JEMPERLI within a certain period of time
- **cCR12:** the percentage of participants who achieved cCR after JEMPERLI and maintained it for at least 12 months

*This does not always mean that the cancer has been cured.

ORR - OVERALL RESPONSE RATE

100% → **50 OUT OF 50** participants achieved cCR after JEMPERLI treatment.

cCR12 - OVER 12 MONTHS

93% → **42 OUT OF 45** participants treated with JEMPERLI achieved cCR that was maintained for 12 months.

AT 3 YEARS

89% → **24 OUT OF 27** participants were free of disease recurrence at 3 years.

- 1 patient had their disease return in the same area and had lymph node surgery
- 1 patient withdrew from the trial, and 1 patient died from an unrelated event during the trial

Important Safety Information (cont'd)

Before receiving JEMPERLI, tell your HCP about all of your medical conditions, including immune system problems such as Crohn's disease, ulcerative colitis, or lupus; received an organ or tissue transplant, including corneal transplant; have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic); have received radiation treatment to your chest area; have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome.

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Potential side effects when taking JEMPERLI

JEMPERLI can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- Lung problems, like cough or shortness of breath
- Intestinal problems, like diarrhea (loose stools) or more frequent bowel movements than usual or severe stomach-area (abdomen) pain or tenderness
- Liver problems, like yellowing of your skin or the whites of your eyes
- Hormone gland problems, like headaches that will not go away or unusual headaches, or eye sensitivity to light
- Kidney problems, like swelling in your ankles or blood in your urine
- Skin problems, like rash or itching
- Problems in other organs and tissues, with symptoms including chest pain, tingling or numbness of the arms or legs, or double vision
- Infusion reactions that can sometimes be severe or life-threatening, with symptoms including chills or shaking, dizziness, or shortness of breath or wheezing
- Rejection of a transplanted organ or tissue
- Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic)

In the AZUR-1 trial, the most common side effects were tiredness, rash, diarrhea, and itchy skin (pruritus).

These are not all of the possible side effects of JEMPERLI.

- 3% of study participants stopped taking JEMPERLI completely, and 19% had their treatment interrupted due to side effects

To learn more about these side effects, talk to your doctor or visit JEMPERLI.com

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What you may expect when starting JEMPERLI

Beginning any cancer treatment may bring uncertainty. Fortunately, you can rely on your care team for guidance throughout your journey. You may also want to review the information below to help you feel more prepared.

How JEMPERLI is given

JEMPERLI is given through an intravenous (IV) infusion. The medical staff will prepare the medicine and then the IV infusion should take about 30 minutes.

How often JEMPERLI is given

Usually every 3 weeks for 9 doses over the course of about 6 months. Remember to mark your calendar for appointments.

- During your infusions, make sure to pay attention to how you are feeling. Sometimes chills or shaking, dizziness, itching or rash, or other reactions can occur. If you feel something out of the ordinary, make sure to tell the nurse or someone at the infusion center right away
- Your healthcare provider will decide how many treatments you need
- Your healthcare provider will do blood tests to check you for side effects
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment

Important Safety Information (cont'd)

If you are pregnant or plan to become pregnant, tell your HCP. JEMPERLI can harm your unborn baby. If you are able to become pregnant, your HCP will give you a pregnancy test before you start treatment. Use an effective birth control method during treatment and for 4 months after your last dose of JEMPERLI. Tell your HCP right away if you become pregnant or think you may be pregnant during treatment with JEMPERLI.

If you are breastfeeding or plan to breastfeed, tell your HCP. It is not known if JEMPERLI passes into your milk. Do not feed with your own milk during treatment with JEMPERLI and for 4 months after your last dose.

Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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Call or see your healthcare provider (HCP) right away if you develop any new or worsening signs or symptoms, including:

Lung problems. Signs and symptoms may include cough, shortness of breath, or chest pain.

Intestinal problems. Signs and symptoms may include diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; or severe stomach-area (abdomen) pain or tenderness.

Liver problems. Signs and symptoms may include yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (tea colored), or bleeding or bruising more easily than usual.

Hormone gland problems. Signs and symptoms may include headaches that will not go away or unusual headaches, eye sensitivity to light, eye problems, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, feeling more hungry or thirsty than usual, urinating more often than usual, hair loss, feeling cold, constipation, your voice gets deeper, dizziness or fainting, changes in mood or behavior such as decreased sex drive, irritability, or forgetfulness.

Kidney problems. Signs and symptoms may include change in the amount or color of your urine, blood in your urine, swelling in your ankles, or loss of appetite.

Skin problems. Signs and symptoms may include rash; itching; skin blistering or peeling; swollen lymph nodes; painful sores or ulcers in your mouth or in your nose, throat, or genital area; fever or flu-like symptoms.

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with JEMPERLI. Call or see your HCP right away for any new or worsening signs or symptoms. Signs and symptoms may include chest pain, irregular heartbeat, shortness of breath, swelling of ankles; persistent or severe muscle pain or weakness, muscle cramps; confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs; double vision, blurry vision, drooping eyelids, sensitivity to light, eye pain, changes in eyesight; low red blood cells, bruising.

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Important Safety Information (cont'd)

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Complications, including graft-versus-host-disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with JEMPERLI. Your HCP will monitor you for these complications.

Getting medical treatment right away may help keep these problems from becoming more serious. Your HCP will check you for these problems during treatment with JEMPERLI and may treat you with corticosteroid or hormone replacement medicines. If you have severe side effects, your HCP may also need to delay or completely stop treatment with JEMPERLI.

Before receiving JEMPERLI, tell your HCP about all of your medical conditions, including immune system problems such as Crohn's disease, ulcerative colitis, or lupus; received an organ or tissue transplant, including corneal transplant; have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic); have received radiation treatment to your chest area; have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome.

If you are pregnant or plan to become pregnant, tell your HCP. JEMPERLI can harm your unborn baby. If you are able to become pregnant, your HCP will give you a pregnancy test before you start treatment. Use an effective birth control method during treatment and for 4 months after your last dose of JEMPERLI. Tell your HCP right away if you become pregnant or think you may be pregnant during treatment with JEMPERLI.

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Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of JEMPERLI in people with MSI-H or dMMR locally advanced rectal cancer (LARC) when used alone include tiredness, rash, diarrhea, itchy skin (pruritus).

These are not all of the possible side effects of JEMPERLI. Call your doctor for medical advice about side effects.

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 negative side effects to GSK at **gsk.public.reportum.com** or 1-888-825-5249.

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FOR PRESCRIBED PATIENTS ONLY

together with | Jemperli (dostarlimab-gxly) Injection 500 mg

Together with JEMPERLI is more than a program—it's our promise to understand your needs, listen to what matters most to you, and create meaningful connections along the way.

Once your doctor has prescribed JEMPERLI, we will help you to understand the medication coverage process, investigate affordable options, and guide you through your care.

Here's what you can expect from **Together with JEMPERLI:**

Coverage Support

We'll check your insurance coverage and help you understand your benefits.* Together with JEMPERLI is here to help you navigate coverage and provide ongoing support.

*The information provided by Together with JEMPERLI is not a guarantee of coverage or payment.

Cost Support

We're here to let you know about the options for help paying for JEMPERLI if you are eligible.

Patient Support

Your Patient Navigator† is at the heart of our program, offering tailored support throughout your treatment journey.

†The Patient Navigator does not provide medical advice and is not a part of your doctor's care team. Please ask your doctor any questions that you might have about your disease and treatment with JEMPERLI.

If you have questions about how to access or pay for JEMPERLI, visit TogetherwithJEMPERLI.com or call 1-800-4GSK-ONC (1-844-447-5662).

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Together with JEMPERLI (cont'd)

For additional Support and Resources, including downloadable brochures, please visit JEMPERLI.com

Once you are enrolled, your **support will be tailored to you**

You Have Cost Support Options

Paying for medicine is not one-size-fits-all. The necessary support can be vastly different depending on your needs and insurance coverage. Together with JEMPERLI offers assistance with finding affordable options like copay or patient assistance programs for eligible patients.

JEMPERLI Copay Program

The JEMPERLI Copay Program helps eligible commercially insured patients with their eligible out-of-pocket costs for JEMPERLI.

You could get JEMPERLI for as little as **$0* PER DOSE.**

*Program annual maximums apply. Visit TogetherwithJEMPERLI.com for information about eligibility and full program terms and conditions.

You Have a Patient Navigator in Your Corner

Your Patient Navigator can answer questions about insurance benefits and out-of-pocket costs. They can help you understand financial assistance and provide you with information about the product.

Refer to TogetherwithJEMPERLI.com for full program terms and conditions.

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Take an active role in your treatment. Ask your doctor about JEMPERLI today. Visit JEMPERLI.com/redefine-options

Important Safety Information (cont'd)

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