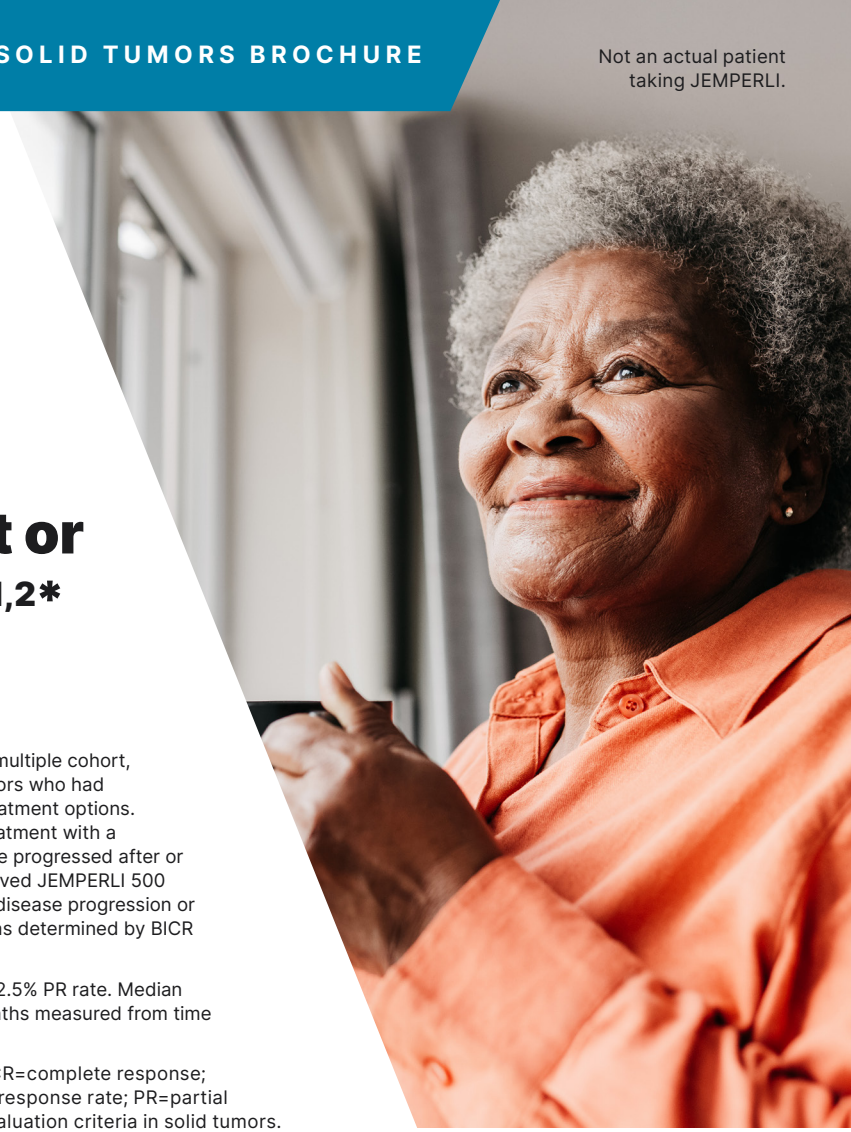
Jemperli (dostarlimab-gxly) Injection 500 mg



Not an actual patient taking JEMPERLI.

Clinically Meaningful Efficacy Demonstrated Across dMMR Recurrent or Advanced Solid Tumors[1,2]*

The efficacy of JEMPERLI was investigated in a nonrandomized, multicenter, multiple cohort, open-label study of 209 patients with dMMR recurrent or advanced solid tumors who had progressed following systemic therapy and had no satisfactory alternative treatment options. Patients with dMMR endometrial cancer must have progressed on or after treatment with a platinum-containing regimen. Patients with dMMR colorectal cancer must have progressed after or been intolerant to a fluoropyrimidine, oxaliplatin, and irinotecan. Patients received JEMPERLI 500 mg via intravenous infusion Q3W for 4 doses followed by 1000 mg Q6W until disease progression or unacceptable toxicity. Major efficacy outcome measures were ORR and DOR as determined by BICR according to RECIST v1.1.[1]

*ORR with JEMPERLI was 41.6% (95% CI: 34.9-48.6) with a 9.1% CR rate and 32.5% PR rate. Median DOR was 34.7 months (range: 2.6, 35.8+) with a median follow-up of 17.5 months measured from time of first response.[1]

+=ongoing at last assessment; BICR=blinded independent central review; CR=complete response; dMMR=mismatch repair deficient; DOR=duration of response; ORR=overall response rate; PR=partial response; Q3W=every 3 weeks; Q6W=every 6 weeks; RECIST=response evaluation criteria in solid tumors.

INDICATIONS

- JEMPERLI, in combination with carboplatin and paclitaxel, followed by JEMPERLI as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC).
- JEMPERLI, as a single agent, is indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced:
  - EC, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or radiation, or
  - solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

- Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue and can occur at any time during or after treatment with a PD-1/PD-L1–blocking antibody, including JEMPERLI.
- Monitor closely for signs and symptoms of immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function tests at baseline and periodically during treatment. For suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

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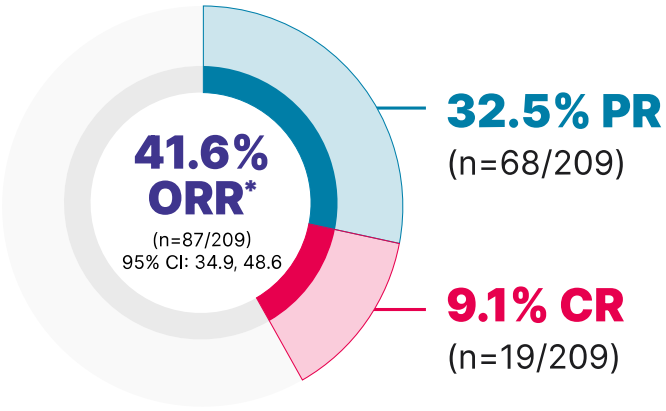
JEMPERLI Showed a 42% Overall Response Rate Across dMMR Recurrent or Advanced Solid Tumors, Including Endometrial Cancer[1,2]

Median follow-up was 17.5 months measured from time of first response[1]

The efficacy of JEMPERLI was investigated in a nonrandomized, multicenter, multiple cohort, open-label study of 209 patients with dMMR recurrent or advanced solid tumors who had progressed following systemic therapy and had no satisfactory alternative treatment options. Patients with dMMR endometrial cancer must have progressed on or after treatment with a platinum-containing regimen. Patients with dMMR colorectal cancer must have progressed after or been intolerant to a fluoropyrimidine, oxaliplatin, and irinotecan. The safety profile of JEMPERLI was investigated in 267 patients with dMMR recurrent or advanced solid tumors enrolled in the trial.[1]

Overall Response Rate (n=209)



Patients with prior treatment with PD-1/PD-L1–blocking antibodies or other immune checkpoint inhibitor therapy and patients with autoimmune disease that required systemic therapy with immunosuppressant agents within 2 years were excluded from the trial.[1]

Patients received JEMPERLI 500 mg via intravenous infusion every 3 weeks for 4 doses followed by 1000 mg every 6 weeks until disease progression or unacceptable toxicity.[1]

The major efficacy outcome measures were ORR and DOR as determined by BICR according to RECIST v1.1.[1]

The efficacy population included those patients with ≥6 months of follow-up time as of March 1, 2020, and with ≥1 measurable lesion at baseline. Additional follow-up on duration of response and safety was taken on November 1, 2020.[2]

*Based on confirmed response by BICR.[1]

CI=confidence interval; CR=complete response; PR=partial response.

IMPORTANT SAFETY INFORMATION (CONT'D)

Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

- Based on the severity of the adverse reaction, withhold or permanently discontinue JEMPERLI. In general, if JEMPERLI requires interruption or discontinuation, administer systemic corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids.

Immune-Mediated Pneumonitis

- JEMPERLI can cause immune-mediated pneumonitis, which can be fatal. In patients treated with other PD-1/PD-L1–blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Pneumonitis occurred in 2.3% (14/605) of patients, including Grade 2 (1.3%), Grade 3 (0.8%), and Grade 4 (0.2%) pneumonitis.

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~3 Year Median Duration of Response Observed With JEMPERLI[1,2]

34.7 Months

median duration of response (range: 2.6, 35.8+)

95.4% of Responders

experienced duration of response ≥6 months

- Median follow-up for duration of response was 17.5 months measured from time of first response
- DOR was evaluated in patients with confirmed partial or complete response by BICR (n=87)

+=ongoing at last assessment.

Response to JEMPERLI Was Observed in 10+ dMMR Tumor Types[1]*

- Endometrial cancer (n=46/103)
- Colorectal cancer (n=25/69)
- Small intestinal cancer (n=4/12)
- Gastric cancers (n=3/8)
- Biliary neoplasm (n=2/2)
- Liver cancer (n=1/2)
- Ovarian cancer (n=1/2)
- Adrenal cortical (n=1/1)
- Breast cancer (n=1/1)
- Malignant neoplasm of the female genitals (n=1/1)
- Pleural (n=1/1)
- Unknown origin (n=1/1)

*Includes patients with a confirmed partial or complete response.[2]

IMPORTANT SAFETY INFORMATION (CONT'D)

Immune-Mediated Colitis

- Colitis occurred in 1.3% (8/605) of patients, including Grade 2 (0.7%) and Grade 3 (0.7%) adverse reactions. Cytomegalovirus infection/reactivation have occurred in patients with corticosteroid-refractory immune-mediated colitis. In such cases, consider repeating infectious workup to exclude alternative etiologies.

Immune-Mediated Hepatitis

- JEMPERLI can cause immune-mediated hepatitis, which can be fatal. Grade 3 hepatitis occurred in 0.5% (3/605) of patients.

Immune-Mediated Endocrinopathies

- Adrenal Insufficiency
  - Adrenal insufficiency occurred in 1.2% (7/605) of patients, including Grade 2 (0.5%) and Grade 3 (0.7%). For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

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Jemperli (dostarlimab-gxly) Injection 500 mg

Safety Profile and Tolerability of JEMPERLI Were Evaluated in Patients With dMMR Recurrent or Advanced Solid Tumors (N=267)[1]

9% of patients permanently discontinued therapy due to adverse reactions[1]

- The most common adverse reaction (≥1%) leading to discontinuation was increased alanine aminotransferase (1.1%)
- The most common adverse reactions (≥20%) were fatigue/asthenia, anemia, diarrhea, and nausea
- Serious adverse reactions occurred in 34% of patients receiving JEMPERLI. Serious adverse reactions in >2% of patients included abdominal pain (3.7%), sepsis (2.6%), and acute kidney injury (2.2%)
- Fatal adverse reaction occurred in 1 patient who received JEMPERLI due to respiratory failure

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

NCCN RECOMMENDATION

National Comprehensive Cancer Network® (NCCN®) recommends dostarlimab-gxly (JEMPERLI) as a subsequent-line systemic treatment option for certain patients with dMMR recurrent or advanced solid tumors.[3-13]*†‡

- Colon cancer
- Gastric cancer
- Hepatocellular carcinoma§
- Biliary tract cancers§
- Rectal cancer
- Uterine neoplasms
- Ovarian cancer
- Breast cancer
- Small bowel adenocarcinoma
- Occult primary cancers
- Esophageal and esophagogastric junction cancers

*As of May 2025. †All recommendations are Category 2A unless otherwise indicated. ‡NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way. §Category 2B recommendation.
Category 2A—Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.
Category 2B—Based upon lower-level evidence, there is NCCN consensus (≥50%, but <85% support of the Panel) that the intervention is appropriate.

IMPORTANT SAFETY INFORMATION (CONT'D)

Immune-Mediated Endocrinopathies (cont'd)

- Hypophysitis
  - JEMPERLI can cause immune-mediated hypophysitis. Grade 3 hypophysitis occurred in 0.4% (1/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 2 hypophysitis occurred in 0.2% (1/605) of patients receiving JEMPERLI as a single agent. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

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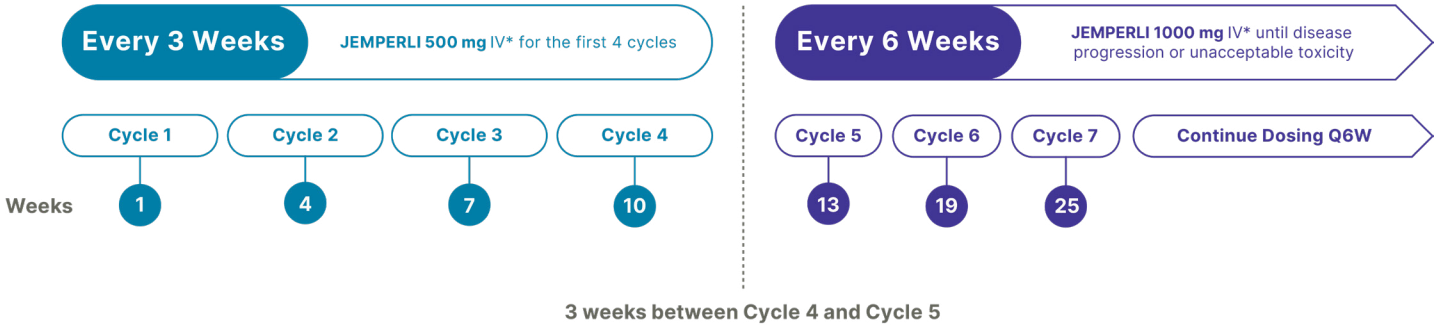
Jemperli (dostarlimab-gxly) Injection 500 mg

After Initial 4 Doses, 6-week Dosing With JEMPERLI[1]

JEMPERLI Given as Monotherapy[1]

Recommended dosage of JEMPERLI in dMMR recurrent or advanced solid tumors[1]



*30-minute intravenous infusion.[1]

IV=intravenous infusion.

IMPORTANT SAFETY INFORMATION (CONT'D)

Immune-Mediated Endocrinopathies (cont'd)

- Thyroid Disorders
  - Grade 2 thyroiditis occurred in 0.5% (3/605) of patients. Grade 2 hypothyroidism occurred in 12% (30/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 2 hypothyroidism occurred in 8% (46/605) of patients receiving JEMPERLI as a single agent. Hyperthyroidism occurred in 3.3% (8/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel, including Grade 2 (2.9%) and Grade 3 (0.4%). Hyperthyroidism occurred in 2.3% (14/605) of patients receiving JEMPERLI as a single agent, including Grade 2 (2.1%) and Grade 3 (0.2%). Initiate thyroid hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.
- Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis
  - JEMPERLI can cause type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Grade 3 type 1 diabetes mellitus occurred in 0.4% (1/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 3 type 1 diabetes mellitus occurred in 0.2% (1/605) of patients receiving JEMPERLI as a single agent. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

Immune-Mediated Nephritis with Renal Dysfunction

- JEMPERLI can cause immune-mediated nephritis, which can be fatal. Grade 2 nephritis, including tubulointerstitial nephritis, occurred in 0.5% (3/605) of patients.

Immune-Mediated Dermatologic Adverse Reactions

- JEMPERLI can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS), have occurred with PD-1/PD-L1–blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/exfoliative rashes. Withhold or permanently discontinue JEMPERLI depending on severity.

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Together with GSK Oncology*†

One source for GSK access and reimbursement resources

Explore the options together—we are here to help

GSK understands the challenges both you and your patients face after their diagnosis. **Together with GSK Oncology** is here to help, offering a variety of access and reimbursement services in one easy-to-access location for all GSK oncology products.

- **Coverage Support**
  - Patient-specific benefits investigation support
  - Prior authorization and appeals support
- **Copay assistance for eligible commercially insured patients**
- **Claims assistance**
- **Patient assistance program (PAP) is available for patients who meet the eligibility criteria‡**
- **Information about other organizations or independent foundations that may be able to help with JEMPERLI costs**

*See full terms and conditions at GSKforYou.com/programs/copay-assistance. ‡The GSK PAP is operated by the GSK Patient Access Programs Foundation, an independent, non-profit organization from GSK.

Together with GSK Oncology

†**Together with GSK Oncology*** provides resources for patients and healthcare professionals. Specific eligibility requirements are determined by the payer; therefore patients and healthcare professionals should confirm information directly with payers. **Together with GSK Oncology** does not guarantee coverage or payer reimbursement.

IMPORTANT SAFETY INFORMATION (CONT'D)

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred in <1% of the 605 patients treated with JEMPERLI or were reported with the use of other PD-1/PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.
  - *Nervous System*: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy
  - *Cardiac/Vascular*: Myocarditis, pericarditis, vasculitis
  - *Ocular*: Uveitis, iritis, other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur
  - *Gastrointestinal*: Pancreatitis, including increases in serum amylase and lipase levels, gastritis, duodenitis
  - *Musculoskeletal and Connective Tissue:* Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica
  - *Endocrine*: Hypoparathyroidism
  - *Other (Hematologic/Immune)*: Autoimmune hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

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References

1. JEMPERLI. Prescribing Information. GSK; 2024. **2.** Berton D, et al. Presented at the American Society of Clinical Oncology virtual meeting; June 4-8, 2021. Poster 2564. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Uterine Neoplasms. V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.* **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer. V.2.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed June 13, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.* **5.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Colon Cancer. V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.* **6.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer. V.4.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.* **7.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Occult Primary. V.2.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.* **8.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Bowel Adenocarcinoma. V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.* **9.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Rectal Cancer. V2.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.* **10.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Gastric Cancer. V.2.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.* **11.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hepatocellular Carcinoma. V.1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.* **12.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Biliary Tract Cancers. V.1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.* **13.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Esophageal and Esophagogastric Junction Cancers. V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed May 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.*

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Your patients can access the information and resources they need at JEMPERLI.com

IMPORTANT SAFETY INFORMATION (CONT'D)

Infusion-Related Reactions

- Severe or life-threatening infusion-related reactions have been reported with PD-1/PD-L1–blocking antibodies. Severe infusion-related reactions (Grade 3) occurred in 0.2% (1/605) of patients receiving JEMPERLI. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue JEMPERLI based on severity of reaction.

Complications of Allogeneic HSCT

- Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after treatment with a PD-1/PD-L1–blocking antibody, which may occur despite intervening therapy. Monitor patients closely for transplant-related complications and intervene promptly.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Embryo-Fetal Toxicity and Lactation

- Based on its mechanism of action, JEMPERLI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JEMPERLI and for 4 months after their last dose. Because of the potential for serious adverse reactions from JEMPERLI in a breastfed child, advise women not to breastfeed during treatment with JEMPERLI and for 4 months after their last dose.

Common Adverse Reactions

The most common adverse reactions (≥20%), including laboratory abnormalities, in patients with EC who received JEMPERLI in combination with carboplatin and paclitaxel were decreased hemoglobin, increased creatinine, peripheral neuropathy, decreased white blood cell count, fatigue, nausea, alopecia, decreased platelets, increased glucose, decreased lymphocytes, decreased magnesium, decreased neutrophils, increased AST, arthralgia, rash, constipation, diarrhea, increased ALT, decreased potassium, decreased albumin, decreased sodium, increased alkaline phosphatase, abdominal pain, dyspnea, decreased appetite, increased amylase, decreased phosphate, urinary tract infection, and vomiting.

The most common adverse reactions (≥20%) in patients with dMMR EC who received JEMPERLI as a single agent were fatigue/asthenia, anemia, nausea, diarrhea, constipation, vomiting, and rash. The most common Grade 3 or 4 laboratory abnormalities (>2%) were decreased lymphocytes, decreased sodium, increased alanine aminotransferase, increased creatinine, decreased neutrophils, decreased albumin, and increased alkaline phosphatase.

The most common adverse reactions (≥20%) in patients with dMMR solid tumors who received JEMPERLI as a single agent were fatigue/asthenia, anemia, diarrhea, and nausea. The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, decreased sodium, increased alkaline phosphatase, and decreased albumin.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

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Produced in USA.
File name: JEMPERLI HCP Brochure

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