Jemperli
(dostarlimab-gxly) Injection 500 mg
Teach Me, Help Me, Know Me, Speak My Language
KNOWLEDGE IS GOLD
See how understanding the JEMPERLI clinical trial results can help you feel more empowered about your care.

Why Knowledge is Gold

Finding out you have endometrial cancer (EC) can be scary. Not only are you facing a life-changing illness, but you're likely overwhelmed by a flood of new information filled with confusing medical terms and concepts about different treatment options.

It would be very difficult to cover the details of every treatment option in one resource. However, **Knowledge is Gold** can help you understand an important clinical trial named **RUBY** that studied one specific medication, **JEMPERLI** in combination with the chemotherapy medicines carboplatin and paclitaxel (CP).

While clinical trials can have similar characteristics, they are all different. This brochure is not a comprehensive overview of all treatment options for EC. It is intended to provide information specifically about JEMPERLI + CP to enable you to make informed decisions about your care with your doctor.

It is important that you talk about all possible treatment options with your doctor.

Approved Uses

JEMPERLI is a prescription medicine used to treat adults with:

- a kind of uterine cancer called endometrial cancer (EC)
  - JEMPERLI may be used in combination with the chemotherapy medicines, carboplatin and paclitaxel, and then after that JEMPERLI may be used alone:
    - when your cancer has spread outside your uterus (advanced) **or**,
    - your cancer has returned.
  - JEMPERLI may be used alone:
    - when a laboratory test shows that your tumor is mismatch repair deficient (dMMR), **and**
    - your cancer has returned, or it has spread (advanced EC), **and**
    - you have received chemotherapy that contains platinum and it did not work or is no longer working, **and**
    - your cancer cannot be treated by surgery or radiation.

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.

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Understanding equals empowerment

Patients who feel they're more aware and educated about their health issues and treatment from the beginning may express more satisfaction with their care.

Having a solid understanding of how a clinical trial like **RUBY** is designed can inform your potential EC path ahead and could lead you to:

- Start detailed and helpful chats with doctors and care teams
- Ask questions with greater confidence
- Have better conversations with care partners, family, and friends
- Make more informed decisions about treatment choices with your doctor

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 or more 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.

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Clinical trial basics for *understanding* RUBY

Before they are approved, medications are required to undergo rigorous testing through clinical trials. Once you understand how a trial works, you'll have a better idea of how or if a treatment may work for a patient like you.

When scientists have reason to believe that a medication can treat, prevent, or manage a disease, that medication is then studied for potential benefits and risks in a clinical trial.

The U.S. Food and Drug Administration (FDA) then reviews data from the trials to determine if the medication will be approved.

What's actually studied in a clinical trial?

Before the trial begins, scientists plan how the trial will be conducted and what the study will measure. These planned measures are called endpoints (more on that later) and can be used to help learn about the potential benefits and risks of the drug.

Who participates in a clinical trial?

Patients can volunteer to join a trial. Known as study participants, they are selected based on many factors including their type of disease, how severe their disease is, and their overall health.

Important Safety Information (cont'd)

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 worse signs or symptoms. Signs and symptoms may include chest pain, irregular heartbeat, shortness of breath, swelling of ankles; 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, sensitivity to light, eye pain, changes in eyesight; persistent or severe muscle pain or weakness, muscle cramps; low red blood cells, bruising.

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What might these results mean for me?

Scientists compare the results from the different study groups at preplanned timepoints during the trial.

If the trial results show that the drug's potential benefits outweigh its known and potential risks for the types of patients included in the trial, then it's **approved** by the FDA. Once the medication is approved, it is available for the healthcare professional and patient to discuss as a potential treatment option.

Important Safety Information (cont'd)

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.

Rejection of a transplanted organ. Your HCP should tell you what signs and symptoms you should report and monitor you, depending on the type of organ 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.

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How the RUBY clinical trial worked

In the **RUBY** clinical trial, the study participants were randomized, or randomly divided, into 2 groups before the trial began.

RUBY was a **double-blind** trial, which means that both the doctors and participants were unaware which group the patients were in. This was done to make sure the results were fair and unbiased.

The 2 groups in the RUBY clinical trial

THE TEST GROUP	THE CONTROL GROUP
Given JEMPERLI, the medication that was studied, plus the standard-of-care chemotherapy medicines CP.	Given a placebo, which is an inactive substance, plus CP.

Why this may be important for certain patients considering or starting treatment with JEMPERLI

RUBY tested the effectiveness and safety of adding the **immunotherapy** JEMPERLI to carboplatin and paclitaxel (CP) for patients with newly-diagnosed advanced or returned EC. The trial treated some patients with JEMPERLI + CP and others with a **placebo** + CP.

Based on the results of RUBY, JEMPERLI + CP was approved by the FDA for doctors to prescribe to patients with newly-diagnosed advanced or returned endometrial cancer.

SPEAK MY LANGUAGE (Understanding the terminology)

Immunotherapy: A treatment that is designed to work with the body's immune system to find and attack cancer cells. It is not chemotherapy or radiation.
Placebo: An inactive substance designed to look like the medicine being tested and taken in the same way (for example, in a pill or as an infusion).

Important Safety Information (cont'd)

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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How JEMPERLI was studied in patients like you

The **RUBY** clinical trial compared JEMPERLI + carboplatin and paclitaxel (CP) in the test group versus CP + placebo in the control group. **RUBY** tested the drug combinations in 494 people with newly-diagnosed advanced or returned EC, also known as the **overall population.**

The overall population in the trial included people with 2 different biomarker categories, **dMMR/MSI-H** or **MMRp/MSS. If you haven't already, talk to your doctor to learn more about biomarker testing and what information it may provide about your disease.**

Test Group

Study participants taking JEMPERLI + CP received:

500 mg of JEMPERLI + CP every 3 weeks for 6 doses

Then 1000 mg of JEMPERLI alone every 6 weeks

Control Group

Study participants taking CP alone received:

CP + placebo (an inactive substance designed to look like the medicine being tested) every 3 weeks for 6 doses

Then placebo alone every 6 weeks

SPEAK MY LANGUAGE (Understanding the terminology)

Overall population of the RUBY trial: Patients with newly-diagnosed advanced or returned endometrial cancer, including those with dMMR/MSI-H or MMRp/MSS biomarker status.

Biomarker: A molecule found in the tissues or fluids of your body that shows if a condition, process, or disease is normal or abnormal.

MMR or mismatch repair: The MMR system corrects mistakes that occur in genes during normal cell growth.

dMMR or mismatch repair deficient: Describes cancers that have an MMR system that is not working properly to correct errors in the genes.

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

MMRp or mismatch repair proficient: Describes cancers that have an MMR system that is working properly to correct errors in the genes.

MSS or microsatellite stable: Describes cancers that have stable genes because the MMR system is working properly to correct errors in the genes.

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 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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Why do I need to know about endpoints?

The endpoints in RUBY measured the potential risks and benefits of taking JEMPERLI.

Most clinical trials include many endpoints, but 2 of the most important endpoints for cancer clinical trials are **overall survival (OS)** and **progression-free survival (PFS).**

In the JEMPERLI clinical trial RUBY, the 2 main endpoints were OS and PFS.

OS

Overall Survival (OS) measures the average length of time patients are alive after the start of treatment. It is considered to be the gold standard measure in cancer clinical trials.

PFS

Progression-Free Survival (PFS) measures a delay or pause in disease progression or refers to the length of time that the study participants experienced without their cancer growing, spreading, or getting worse.

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 breast milk. Do not breastfeed 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.

The most common side effects of JEMPERLI when given with carboplatin and paclitaxel include nerve problems in your arms, hands, legs, and feet; tiredness; nausea; hair loss; joint pain; rash; constipation; diarrhea; stomach-area (abdomen) pain; shortness of breath; decreased appetite; urinary tract infections; vomiting.

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Overall Survival or OS is one way to measure how well a treatment works

OS was one of the main endpoints in the RUBY clinical trial for JEMPERLI.

OS is the GOLD STANDARD measure for cancer clinical trials

JEMPERLI + CP has achieved that OS gold standard measure by showing a treatment benefit in OS.

In the overall study population, median OS with JEMPERLI + CP was 45 months vs 28 months with CP alone.* A total of 136 out of 245 participants treated with JEMPERLI + CP were still alive, compared with 105 out of 249 treated with CP alone.

Another main endpoint in the RUBY trial was progression-free survival, or PFS.

In the overall study population, participants receiving JEMPERLI + CP experienced a median of 12 months without their cancer growing, spreading, or getting worse compared with 8 months for those on CP alone.* A total of 110 out of 245 participants treated with JEMPERLI + CP didn't experience their cancer growing, spreading, or getting worse compared with 72 out of 249 treated with CP alone.

*These differences are statistically significant, which means that the differences between the 2 treatment groups are greater than what might be expected by chance alone. Results varied among different biomarker groups within the overall population. Median is the middle value in a set of measurements. JEMPERLI + CP was not studied in comparison to other immunotherapy combinations.

Learn about additional trial results at JEMPERLI.com.

Important Safety Information (cont'd)

The most common side effects of JEMPERLI when used alone include tiredness and weakness, low red blood cell count (anemia), diarrhea, nausea, constipation, vomiting.

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 by calling 1-800-FDA-1088 or visiting www.fda.gov/medwatch.

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Be a self-advocate, make decisions with your doctor

Endometrial cancer treatment decisions should only be made after you and your doctor discuss options together.

YOUR VOICE MATTERS!

Stay empowered when meeting with your doctor to make sure your questions are answered and your concerns are heard.

Here are some questions you may want to ask your care team early in your treatment journey:

- What are my treatment goals?
- What are the appropriate treatment options for me?
- What are some of the side effects for JEMPERLI?
- How long will I have to be on treatment?
- How will I know if my treatment is working?
- What is my biomarker status, and how are biomarkers important?
- What can you tell me about the available data for my treatment options?

Important Safety Information

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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 or more 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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Take note of *your thoughts*

Please use this space to write down any of the following you would like to address with your care team.

- Any questions you may have
- Concerns about what you read
- Things you didn't understand
- Anything else you want to learn more about

If you're viewing this page on a digital device, please type in the fields provided, or print this page and write on the lines.

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Take advantage of these helpful *resources*

Educational resources for you and your care partner are available at JEMPERLI.com. Explore additional online resources below.

Information about cancer

American Cancer Society
cancer.org

Please note: These resources are external to GSK. GSK does not have control over the content or information provided through these resources and accordingly does not warrant their accuracy or completeness. These organizations, including American Cancer Society, do not endorse any products or services.

Support and advocacy

CancerCare
cancercare.org

Cancer Support Community
cancersupportcommunity.org

Patient Empowerment Network
powerfulpatients.org

SHARE Cancer Support
sharecancersupport.org

Additional JEMPERLI resources

JEMPERLI Patient Brochure
Learn more about JEMPERLI in this informative brochure, ready to download or print.

JEMPERLI Glossary
To provide you with a better understanding of the terms, acronyms, and phrases that may be frequently used by your care team, ready to download or print.

Important Safety Information (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.

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Stay informed and *empowered*

If you're ever unsure or confused about your treatment, feel confident to ask your care team questions. Because KNOWLEDGE IS GOLD!

Hopefully you now have a better understanding of how medications are tested including JEMPERLI. Armed with this knowledge, remember to talk to your doctor about what may be right for you as you consider or start your treatment with JEMPERLI.

OS is the GOLD STANDARD measure for cancer clinical trials

JEMPERLI + CP has achieved that OS gold standard measure by showing a treatment benefit in OS.

In the overall study population of the **RUBY** trial, median OS with JEMPERLI + CP was 45 months vs 28 months with CP alone. This difference is statistically significant, which means that the difference between the two treatment groups is greater than what might be expected by chance alone. Results varied among different biomarker groups within the overall population. Median is the middle value in a set of measurements. JEMPERLI + CP was not studied in comparison to other immunotherapy combinations.

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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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