Package leaflet: Information for the patient

JEMPERLI 500 mg concentrate for solution for infusion
dostarlimab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Your doctor will provide you with a Patient Card. Be sure to keep this Card with you while undergoing treatment with JEMPERLI.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What JEMPERLI is and what it is used for
2. What you need to know before you are given JEMPERLI
3. How JEMPERLI is given
4. Possible side effects
5. How to store JEMPERLI
6. Contents of the pack and other information

1. What JEMPERLI is and what it is used for

JEMPERLI contains the active substance dostarlimab, which is a *monoclonal antibody*, a type of protein designed to recognise and attach to a specific target substance in the body.

JEMPERLI works by helping your immune system fight your cancer.

JEMPERLI is used in adults to treat a kind of cancer called *endometrial cancer* (cancer of the lining of the womb) that has a tumour abnormality called mismatch repair deficient (dMMR) / microsatellite instability-high (MSI-H).

JEMPERLI is given on its own when the cancer has spread, or cannot be taken out by surgery, and has progressed on or following prior treatment with chemotherapy.

JEMPERLI is given in combination with chemotherapy when the cancer is advanced (meaning it has spread) at the time it is first diagnosed or if it is recurrent (meaning it was treated and has returned).

It is important that you also read the package leaflets for the other anticancer medicines you may be receiving. If you have any questions about these medicines, ask your doctor.

2. What you need to know before you are given JEMPERLI

You should not be given JEMPERLI:
- if you are allergic to dostarlimab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or nurse before you are given JEMPERLI if you have:

- immune system problems;
- lung or breathing problems;
- liver or kidney problems;
- serious rash;
- any other medical problems.

Symptoms you need to look out for
JEMPERLI can have serious side effects, which can sometimes become life-threatening and can lead to death. These side effects may happen at any time during treatment, or even after your treatment has ended. You may get more than one side effect at the same time.

You need to be aware of possible symptoms, so your doctor can give you treatment for side effects if necessary.

➔**Read the information** under 'Symptoms of serious side effects' in section 4. Talk to your doctor or nurse if you have any questions or worries.

Children and adolescents
JEMPERLI should not be used in children and adolescents below 18 years of age.

Other medicines and JEMPERLI
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

Some medicines may interfere with the effect of JEMPERLI:
- medicines that make your immune system weak — for example, *corticosteroids*, such as prednisone.

→ **Tell your doctor** if you are taking any of these.

However, once you are treated with JEMPERLI, your doctor may give you corticosteroids to reduce any side effects that you may have.

Pregnancy
- **You must not be given JEMPERLI if you are pregnant** unless your doctor specifically recommends it.
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.
- JEMPERLI can cause harmful effects or death to your unborn baby.
- If you are a woman who could become pregnant, you must use effective **contraception** while you are being treated with JEMPERLI and for at least 4 months after your last dose.

Breast-feeding
- If you are breast-feeding, **ask your doctor** for advice before you are given this medicine.
- **You must not breast-feed** during treatment and for at least 4 months after your last dose of JEMPERLI.
- It is not known if the active ingredient of JEMPERLI passes into your breast milk.

Driving and using machines
JEMPERLI is unlikely to affect your ability to drive and use machines. However, if you have side effects that affect your ability to concentrate and react, you should be careful when driving or operating machines.

JEMPERLI contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free.' However, before JEMPERLI is given to you, it is mixed with a solution that may contain sodium. Talk to your doctor if you are on a low salt diet.

3. How JEMPERLI is given

JEMPERLI will be given to you in a hospital or clinic under the supervision of a doctor experienced in cancer treatment.

When JEMPERLI is given on its own, the recommended dose of JEMPERLI is 500 mg every 3 weeks for 4 doses, followed by 1000 mg every 6 weeks for all doses thereafter.

When JEMPERLI is given in combination with chemotherapy, the recommended dose of JEMPERLI is 500 mg every 3 weeks for 6 doses, followed by 1000 mg every 6 weeks for all doses thereafter. Your doctor will tell you how the chemotherapy treatment is given.

Your doctor will give you JEMPERLI as a drip into a vein *(intravenous infusion)* for about 30 minutes.

Your doctor will decide how many treatments you need.

If you forget an appointment to receive JEMPERLI

➔ **Contact your doctor or hospital immediately** to reschedule your appointment.

It is very important that you do not miss a dose of this medicine.

If you stop receiving JEMPERLI
Stopping your treatment may stop the effect of the medicine. Do not stop treatment with JEMPERLI unless you have discussed this with your doctor.

Patient Card
Important information from this Package Leaflet can be found in the Patient Card you have been given by your doctor. It is important that you keep this Patient Card and show it to your partner or caregivers.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some of the side effects can be serious, and you need to know what symptoms to look out for.

Symptoms of serious side effects
JEMPERLI can cause serious side effects. If you develop symptoms **you must tell your doctor or nurse as soon as possible.** Your doctor may give you other medicines to prevent more serious complications and reduce your symptoms. Your doctor may decide that you should miss a dose of JEMPERLI, or stop your treatment altogether.

Conditions	**Possible symptoms**
Inflammation of lungs *(pneumonitis)*	• shortness of breath • chest pain • new or worse cough

Conditions	Possible symptoms
Inflammation of intestines *(colitis, enteritis, vasculitis gastrointestinal)*	• diarrhoea, or more bowel movements than usual • black, tarry, sticky stools; blood or mucus in stools • severe stomach pain or tenderness • feeling sick *(nausea)*, being sick *(vomiting)*
Inflammation of food pipe and stomach *(oesophagitis, gastritis)*	• trouble swallowing • decreased appetite • burning in the chest (heartburn) • chest or upper belly pain • feeling sick (*nausea*), being sick (*vomiting*)
Inflammation of liver *(hepatitis)*	• feeling sick *(nausea)*, being sick *(vomiting)* • loss of appetite • pain on the right side of the abdomen (stomach) • yellowing of the skin or the whites of the eyes • dark-coloured urine • bleeding or bruising more easily than normal
Inflammation of hormone glands *(especially thyroid, pituitary, adrenal, pancreas)*	• rapid heartbeat • weight loss or weight gain • increased sweating • hair loss • feeling cold • constipation • abdominal pain • deeper voice • muscle aches • dizziness or fainting • headache that will not go away or unusual headache
Type 1 diabetes, including diabetic ketoacidosis (acid in the blood produced from diabetes)	• feeling more hungry or thirsty than usual • needing to urinate more often including at night • weight loss • feeling sick *(nausea)*, being sick *(vomiting)* • stomach pain • feeling tired • unusual sleepiness • having difficulty thinking clearly • breath that smells sweet or fruity • deep or fast breathing
Inflammation of kidneys *(nephritis)*	• changes in amount or colour of urine • swelling of the ankles • loss of appetite • blood in the urine
Inflammation of skin	• rash, itching, dry skin, peeling or skin sores • ulcers in the mouth, nose, throat or genital area
Inflammation of heart muscle *(myocarditis)*	• trouble breathing • dizziness or fainting • fever • chest pain and chest tightness • flu like symptoms
Inflammation of brain and nervous system *(myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, encephalitis)*	• neck stiffness • headache • fever, chills • vomiting • eye sensitivity to light

Conditions	Possible symptoms
	• weakness of eye muscles, drooping eyelids • dry eyes and blurred vision • difficulty swallowing, dry mouth • impaired speech • confusion and sleepiness • dizziness • pricking or pins and needles sensations in the hands and feet • aching muscles • difficulty walking or lifting objects • abnormal heart beat/rate or blood pressure
Inflammation of spinal cord *(myelitis)*	• pain • numbness • tingling, or weakness in the arms or legs • bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation
Inflammation of eyes	• changes in eyesight
Inflammation of other organs	• severe or persistent muscle or joint pains • severe muscle weakness • swollen or cold hands or feet • feeling tired

Infusion-related reactions
Some people may have allergic-like reactions when they receive an infusion. These usually develop within minutes or hours but may develop up to 24 hours after treatment.

Symptoms include:
- shortness of breath or wheezing;
- itching or rash;
- flushing;
- dizziness;
- chills or shaking;
- fever;
- drop in blood pressure (feeling like passing out).

Solid organ transplant rejection and other 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 healthcare provider will monitor you for these complications.

➔ **Seek medical attention immediately** if you think you may be having a reaction.

The following side effects have been reported with JEMPERLI alone.

Very common side effects - (may affect **more than 1 in 10** people):
- decrease in the number of red blood cells *(anaemia);*
- reduced thyroid gland activity;
- diarrhoea; feeling sick *(nausea)*; being sick *(vomiting);*
- skin redness or rash; blistering of the skin or mucous membranes; itchy skin;
- joint pain;

- high temperature; fever;
- increased liver enzyme levels in the blood.

➔ **Check the table** above for symptoms of possible serious side effects.

Common side effects - (may affect **up to 1 in 10** people):
- overactive thyroid gland;
- decreased secretion of adrenal hormones *(adrenal insufficiency);*
- inflammation of the lung;
- inflammation of the lining of the bowel *(colon)*;
- inflammation of the pancreas;
- inflammation of the stomach;
- inflammation of the liver;
- muscle pain;
- chills;
- reaction to the infusion;
- hypersensitivity reaction to the infusion.

➔ **Check the table** above for symptoms of possible serious side effects.

Uncommon side effects - (may affect **up to 1 in 100** people):
- inflammation of the brain;
- destruction of red blood cells (*Autoimmune haemolytic anaemia*);
- inflammation of the pituitary gland, in the base of the brain;
- inflammation of the thyroid gland;
- Type 1 diabetes or diabetic complications *(diabetic ketoacidosis);*
- inflammation of the food pipe;
- a condition in which the muscles become weak and there is a rapid fatigue of the muscles (*myasthenia gravis*);
- inflammation of the joints;
- inflammation of the muscles;
- inflammation of the eye — the iris (the coloured part of the eye) and the ciliary body (area around the iris);
- inflammation of the kidneys.

➔ **Check the table** above for symptoms of possible serious side effects.

The following side effects have been reported with JEMPERLI when given in combination with chemotherapy.

Very common side effects - (may affect **more than 1 in 10** people):
- underactive thyroid gland
- skin rash
- dry skin
- high temperature; fever
- increased liver enzyme levels in the blood.

➔ **Check the table** above for symptoms of possible serious side effects.

Common side effects - (may affect **up to 1 in 10** people):
- overactive thyroid gland
- decreased secretion of adrenal hormones
- inflammation of the lung
- inflammation of the lining of the bowel *(colon)*.

➔ **Check the table** above for symptoms of possible serious side effects.

Uncommon side effects - (may affect **up to 1 in 100** people):
- inflammation of the thyroid gland
- Type 1 diabetes or diabetic complications

- a condition in which the muscles become weak and there is a rapid fatigue of the muscles *(myasthenic syndrome)*
- inflammation of the heart muscle
- inflammation of the pancreas
- inflammation of the stomach
- inflammation of the blood vessels in the food pipe, stomach or bowel
- inflammation of the eye
- inflammation of the joints
- inflammation of the muscles
- inflammation throughout the body.

➔ **Check the table** above for symptoms of possible serious side effects.

➔ **Contact your doctor or nurse as soon as possible** if you develop any of these symptoms.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store JEMPERLI

JEMPERLI will be given to you in a hospital or clinic and the healthcare professionals will be responsible for its storage.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Store in the original package in order to protect from light.

If not used immediately, the prepared infusion may be stored for up to 24 hours at 2 °C to 8 °C or 6 hours at room temperature (up to 25 °C) from the time of preparation/dilution until the end of administration.

Do not use if this medicine contains visible particles.

Do not store any unused medicine for reuse. Any unused medicine or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. Contents of the pack and other information

What JEMPERLI contains

- The active substance is dostarlimab.

- One vial of 10 mL concentrate for solution for infusion (sterile concentrate) contains 500 mg of dostarlimab.

- Each mL of concentrate for solution for infusion contains 50 mg of dostarlimab.

- The other ingredients are trisodium citrate dihydrate; citric acid monohydrate; L-arginine hydrochloride; sodium chloride; polysorbate 80; and water for injection (see section 2).

What JEMPERLI looks like and contents of the pack

JEMPERLI is a clear to slightly opalescent colourless to yellow solution, essentially free from visible particles.

It is available in cartons containing one glass vial.

Marketing Authorisation Holder
GlaxoSmithKline UK Limited
980 Great West Road
Brentford
Middlesex
TW8 9GS
UK

Manufacturer
Glaxo Operations UK Ltd.
(trading as Glaxo Wellcome Operations)
Harmire Road
Barnard Castle
DL12 8DT
United Kingdom

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name: **Jemperli**
Reference number: 19494/0297

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in January 2024

The following information is intended for healthcare professionals only:

Preparation/dilution, storage and administration of the solution for infusion:

- Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration. JEMPERLI is a slightly opalescent colourless to yellow solution. Discard the vial if visible particles are observed.
- JEMPERLI is compatible with an IV bag made of polyvinyl chloride (PVC) with or without di(2-ethylhexyl) phthalate (DEHP), ethylene vinyl acetate, polyethylene (PE), polypropylene (PP) or polyolefin blend (PP+PE), and a syringe made from PP.
- For the 500 mg dose, withdraw 10 mL of JEMPERLI from a vial and transfer into an intravenous bag containing sodium chloride 9 mg/mL (0.9 %) solution for injection or glucose 50 mg/mL (5 %) solution for injection. The final concentration of the diluted solution should be between 2 mg/mL and 10 mg/mL. This may require withdrawing a volume of diluent from the IV bag prior to adding a volume of JEMPERLI into the IV bag.
  - For example, if preparing a 500 mg dose in a 250 mL diluent IV bag, to achieve a 2 mg/mL concentration would require withdrawing 10 mL of diluent from the 250 mL IV bag. Then, 10 mL of JEMPERLI would be withdrawn from the vial and transferred into the IV bag.
- For the 1000 mg dose, withdraw 10 mL of JEMPERLI from each of two vials (withdraw 20 mL total) and transfer into an intravenous bag containing sodium chloride 9 mg/mL (0.9 %) solution for injection or glucose 50 mg/mL (5 %) solution for injection. The final concentration of the diluted solution should be between 2 mg/mL and 10 mg/mL. This may require withdrawing a volume of diluent from the IV bag prior to adding a volume of JEMPERLI into the IV bag.
  - For example, if preparing a 1000 mg dose in a 500 mL diluent IV bag, to achieve a 2 mg/mL concentration would require withdrawing 20 mL of diluent from the 500 mL IV bag. Then, 10 mL of JEMPERLI would be withdrawn from each of two vials, totaling 20 mL, and transferred into the IV bag.
- Mix diluted solution by gentle inversion. Do not shake the final infusion bag. Discard any unused portion left in the vial.
- Store in the original carton until time of preparation in order to protect from light. The prepared dose may be stored either:
  - At room temperature up to 25 ºC for no more than 6 hours from the time of dilution until the end of infusion.
  - Under refrigeration at 2 °C – 8 °C for no more than 24 hours from time of dilution until end of infusion. If refrigerated, allow the diluted solution to come to room temperature prior to administration.
- JEMPERLI should be administered by intravenous infusion using an intravenous infusion pump over 30 minutes by a health care practitioner.
- Tubing should be made of PVC, platinum cured silicon or PP; fittings made from PVC or polycarbonate and needles made from stainless steel.
- A 0.2 or 0.22 micron in-line polyethersulfone (PES) filter must be used during administration of JEMPERLI.
- JEMPERLI must not be administered as an intravenous push or bolus injection.
- Do not co-administer other medicinal products through the same infusion line.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.