PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

JEMPERLI

Concentrate for solution for infusion

Each 1 ml contains:

50 mg of dostarlimab

(Each vial contains 10 mL concentrate for solution for infusion which contains 500 mg of dostarlimab).

In addition to the leaflet, JEMPERLI has a Patient Card that will be provided to you by your physician. This Card contains important safety information that you must know before you start the treatment and during treatment with JEMPERLI and follow its instructions. Read the Patient Card and the patient package insert before you start to take the medicine. It is important that you keep the Patient Card for additional review if necessary and to show it to your partner or caregivers.

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – "Important information about some of the ingredients in the medicine" and section 6 – "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

JEMPERLI is indicated in combination with carboplatin and paclitaxel for the treatment of adult patients with mismatch repair deficient (dMMR)/ microsatellite instability high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy.

JEMPERLI is indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.

Therapeutic group: anti-neoplastic agents, monoclonal antibodies, antibody drug conjugates.

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 may be given in combination with other anticancer medicines. 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 physician.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- you are sensitive (allergic) to dostarlimab or to any of the additional ingredients contained in this medicine (listed in section 6).

Special warnings regarding use of the medicine
Before the treatment with JEMPERLI, tell the physician 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 physician can give you treatment for side effects if necessary.

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

Children and adolescents

This medicine should not be used in children and adolescents below 18 years of age.
There is no available data about the safety and efficacy of this medicine in children and adolescents under 18 years of age.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.

Some medicines may interfere with the effect of JEMPERLI:

- medicines that make your immune system weak, for example, corticosteroids, such as prednisone.

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

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

Pregnancy and breast-feeding

Pregnancy

You must not be given JEMPERLI if you are pregnant, unless your physician specifically recommends it.

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your physician for advice before using 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 physician** 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

It is unlikely that this medicine will affect your ability to drive or 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.

Important information about some of the ingredients in the medicine

JEMPERLI contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, 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 physician if you are on a low salt diet.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

JEMPERLI will be given to you in a hospital or clinic under the supervision of a physician 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 1,000 mg every 6 weeks for all doses thereafter.

When JEMPERLI is given in combination with carboplatin and paclitaxel, the recommended dose of JEMPERLI is 500 mg every 3 weeks for 6 doses, followed by 1,000 mg every 6 weeks for all doses thereafter.
Your physician will give you JEMPERLI as a drip into a vein (intravenous infusion) for about 30 minutes.
Your physician will decide how many treatments you need.

Do not exceed the recommended dose.

If you forget an appointment to receive JEMPERLI

→ **Contact your physician 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. Even if there is an improvement in your condition, do not stop treatment with JEMPERLI unless you have discussed this with your physician.

Adhere to the treatment regimen recommended by your physician.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of JEMPERLI may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of 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 physician or nurse as soon as possible.** Your physician may give you other medicines to prevent more serious complications and reduce your symptoms. Your physician 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
Inflammation of intestines (colitis, enteritis, vasculitis [inflammation of the blood vessels] 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 • 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 physician 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

These may affect **more than 1 in 10** people:

• decrease in the number of red blood cells (anaemia)
• reduced thyroid gland activity
• diarrhoea, nausea, 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

These 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

These 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.

Other side effects that have been reported (frequency not known):

- Coeliac disease (characterised by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)
- Lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency).

The following side effects have been reported with JEMPERLI when given in combination with carboplatin and paclitaxel.

Very common side effects

These 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

These 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)

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

Uncommon side effects

These may affect **up to 1 in 100** people:

• inflammation of the thyroid gland
• type 1 diabetes
• 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.

Other side effects that have been reported (frequency not known):
• Coeliac disease (characterised by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)
• Lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency).

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

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

• JEMPERLI will be given to you in a hospital or clinic and the healthcare professional will be responsible for its storage.
• Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to

avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C to 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. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:
  L-arginine hydrochloride, trisodium citrate dihydrate, sodium chloride, citric acid monohydrate, polysorbate 80, water for injection
- What the medicine looks like and the contents of the package:
  JEMPERLI is a clear to slightly opalescent colourless to yellow solution, essentially free from visible particles.
  One carton package contains one vial.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva
- Manufacturer: GlaxoSmithKline Trading Services Limited, Dublin, Ireland.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 169-79-36883

Revised in August 2024.

Jemperli PT V6B 28263

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. The total volume of the infusion solution must not exceed 250 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 1,000 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 4 mg/mL and 10 mg/mL. The total volume of the infusion solution must not exceed 250 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 250 mL diluent IV bag, to achieve a 4 mg/mL concentration would require withdrawing 20 mL of diluent from the 250 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.