

# JEMPERLI

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## 1. What is JEMPERLI and what is it used for?

JEMPERLI contains the active ingredient dostarlimab. JEMPERLI is used to treat endometrial cancer.

For more information, see Section [1. What is JEMPERLI and what is it used for?](#) in the full CMI.

## 2. What should I know before I am given JEMPERLI?

Do not use if you have ever had an allergic reaction to JEMPERLI or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given JEMPERLI?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with JEMPERLI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How will JEMPERLI be given to me?**

JEMPERLI will be given to you in a hospital or clinic under the supervision of a doctor experienced in cancer treatment. More instructions can be found in Section [4. How will JEMPERLI be given to me?](#) in the full CMI.

### **5. What should I know while using JEMPERLI?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Remind any doctor, dentist or pharmacist you visit that you are using JEMPERLI.</li><li>● Seek medical attention if you think you may</li></ul>
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	<p>be having an allergic reaction.</p> <ul style="list-style-type: none"> <li>● If you miss an appointment, contact your doctor or hospital immediately to reschedule.</li> <li>● Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.</li> <li>● Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.</li> <li>● If you are breast-feeding tell your doctor before treatment.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not stop using this medicine suddenly.</li> <li>● It is very important that you do not miss a dose of this medicine.</li> <li>● Do not breast feed during treatment.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● JEMPERLI is unlikely to affect your ability to drive and use machines. However, if you have side effects</li> </ul>

	that affect your ability to concentrate and react, you should be careful when driving or operating machines.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• JEMPERLI will be given to you in a hospital or clinic and the healthcare professionals will be responsible for its storage.</li> </ul>

For more information, see Section [5. What should I know while using JEMPERLI?](#) in the full CMI.

## 6. Are there any 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. JEMPERLI can cause serious side effects due to inflammation. **If you develop symptoms of inflammation, 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



- ▼ 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. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

## JEMPERLI

**Active ingredient: Dostarlimab**

**JEMPERLI has provisional approval in Australia to treat a kind of cancer called endometrial cancer (cancer of the lining of the womb). The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.**

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### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using JEMPERLI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using JEMPERLI.**

**Where to find information in this leaflet:**

- [1. What is JEMPERLI and what is it used for?](#)
  - [2. What should I know before I am given JEMPERLI?](#)
  - [3. What if I am taking other medicines?](#)
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[4. How will JEMPERLI be given to me?](#)

[5. What should I know while using JEMPERLI?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

## **1. What is JEMPERLI and what is it used for?**

**JEMPERLI contains the active ingredient dostarlimab.** Dostarlimab 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.

## **2. What should I know before I am given JEMPERLI?**

### **Warnings**

#### **Do not use JEMPERLI if:**

- you are allergic to dostarlimab, or any of the ingredients listed at the end of this leaflet
- always check the ingredients to make sure you can use this medicine

#### **Check with your doctor if you:**

- have any other medical conditions
- have immune system problems

- have lung or breathing problems
- have liver or kidney problems
- have any other medical problems
- have serious rash
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

You must not be treated with JEMPERLI if you are pregnant unless your doctor specifically recommends it.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You must not breastfeed during your treatment and for at least 4 months after your last dose. It is not known if JEMPERLI passes into your breast milk.

## Patient Card

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

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with JEMPERLI and affect how it works.**

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

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect JEMPERLI.**

## 4. How will JEMPERLI be given to me?

### How much will be given

- JEMPERLI will be given to you in a hospital or clinic under the supervision of a doctor experienced in cancer treatment.
- The recommended dose of JEMPERLI is 500 mg every 3 weeks for 4 doses, followed by 1000 mg every 6 weeks for all cycles thereafter.

### When JEMPERLI will be 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 miss a dose of JEMPERLI

JEMPERLI should be used regularly at the same time as scheduled by your doctor. **It is very important that you do not miss a dose of this medicine.**

If you miss your dose at the usual time, contact your doctor or hospital immediately to reschedule your appointment.

## **5. What should I know while using JEMPERLI?**

### **Things you should do**

- Remind any doctor, dentist or pharmacist you visit that you are using JEMPERLI.
- If you miss an appointment, contact your doctor or hospital immediately to reschedule.
- Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.
- Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.

### **Call your doctor straight away if you:**

- think you may be having an allergic reaction
- notice any symptoms listed in section 6

### **Things you should not do**

- Do not stop using this medicine suddenly.
- It is very important that you do not miss a dose of this medicine.
- Do not breastfeed during treatment.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how JEMPERLI affects you.**

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.

## **Looking after your medicine**

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

The medicine will be stored in the original container in a refrigerator at 2°C to 8°C.

## **Getting rid of any unwanted medicine**

Your healthcare professional will be responsible for discarding JEMPERLI.

## **When to discard your medicine (as relevant)**

JEMPERLI is for single use in one patient only. Any residue will be discarded by your healthcare professional.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Serious side effects**

JEMPERLI can cause serious side effects particularly due to inflammation. The symptoms of inflammation are listed below. If you develop symptoms of inflammation, **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.

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Inflammation of the lungs:</b></p> <ul style="list-style-type: none"> <li>• shortness of breath</li> <li>• chest pain</li> <li>• new or worse cough (pneumonitis)</li> </ul> <p><b>Inflammation of the intestines:</b></p> <ul style="list-style-type: none"> <li>• diarrhoea, or more bowel movements than usual</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● black, tarry, sticky stools; blood or mucus in stools</li> <li>● severe stomach pain or tenderness</li> <li>● feeling sick (nausea), being sick (vomiting)</li> </ul> <p><b>Inflammation of the Liver:</b></p> <ul style="list-style-type: none"> <li>● feeling sick (nausea), being sick (vomiting)</li> <li>● loss of appetite</li> <li>● pain on the right side of the abdomen (stomach)</li> <li>● yellowing of the skin or the whites of the eyes</li> <li>● dark coloured urine</li> <li>● bleeding or bruising more easily than normal</li> </ul> <p><b>Inflammation of the hormone glands:</b></p> <ul style="list-style-type: none"> <li>● rapid heartbeat</li> <li>● weight loss or weight gain</li> <li>● increased sweating</li> <li>● hair loss</li> <li>● feeling cold</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● constipation</li> <li>● abdominal pain</li> <li>● deeper voice</li> <li>● muscle aches</li> <li>● dizziness or fainting</li> <li>● headache that will not go away or unusual headache</li> </ul> <p><b>Inflammation of the kidneys:</b></p> <ul style="list-style-type: none"> <li>● changes in amount or colour of urine</li> <li>● swelling of the ankles</li> <li>● loss of appetite</li> <li>● blood in the urine</li> </ul> <p><b>Inflammation of the skin:</b></p> <ul style="list-style-type: none"> <li>● rash, itching, peeling or skin sores</li> <li>● ulcers in the mouth, nose, throat or genital area</li> </ul> <p><b>Inflammation of the heart muscle (myocarditis):</b></p> <ul style="list-style-type: none"> <li>● trouble breathing</li> <li>● dizziness or fainting</li> <li>● fever</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● chest pain and chest tightness</li> <li>● flu like symptoms.</li> </ul> <p><b>Inflammation of Brain and nervous system (myasthenic syndrome/ myasthenia gravis, Guillain-Barré syndrome, encephalitis):</b></p> <ul style="list-style-type: none"> <li>● neck stiffness</li> <li>● headache</li> <li>● fever, chills</li> <li>● vomiting</li> <li>● eye sensitivity to light</li> <li>● weakness of eye muscles, drooping eyelids</li> <li>● dry eyes and blurred vision</li> <li>● difficulty swallowing, dry mouth</li> <li>● impaired speech</li> <li>● confusion and sleepiness</li> <li>● dizziness</li> <li>● pricking or pins and needles sensations in the hands and feet</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● aching muscles</li> <li>● difficulty walking or lifting objects</li> <li>● abnormal heartbeat/rate or blood pressure</li> </ul> <p><b>Inflammation of the Spinal cord (myelitis):</b></p> <ul style="list-style-type: none"> <li>● pain</li> <li>● numbness</li> <li>● tingling, or weakness in the arms or legs</li> <li>● bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation</li> </ul> <p><b>Inflammation of the eye:</b></p> <ul style="list-style-type: none"> <li>● changes in eyesight</li> </ul> <p><b>Inflammation of other organs:</b></p> <ul style="list-style-type: none"> <li>● severe or persistent muscle or joint pains</li> <li>● severe muscle weakness</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● swollen or cold hands or feet</li> <li>● feeling tired</li> <li>● Infusion-related reactions</li> </ul> <p><b>Anaemia</b></p> <ul style="list-style-type: none"> <li>● shortness of breath</li> <li>● feeling tired</li> </ul> <p><b>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.</b></p> <p><b>Symptoms include:</b></p> <ul style="list-style-type: none"> <li>● shortness of breath or wheezing</li> <li>● itching or rash</li> <li>● flushing</li> <li>● dizziness</li> <li>● chills or shaking</li> <li>● fever</li> <li>● drop in blood pressure (feeling like passing out).</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p data-bbox="199 257 774 824"><b>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).</b></p> <ul data-bbox="199 862 782 1478" style="list-style-type: none"> <li data-bbox="199 862 782 1478">• 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.</li> </ul>	

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

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What JEMPERLI contains

<b>Active ingredient (main ingredient)</b>	Dostarlimab
<b>Other ingredients (inactive ingredients)</b>	sodium citrate, dihydrate; citric acid, monohydrate; arginine hydrochloride; sodium chloride;

	polysorbate 80; and water for injection
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**Tell your doctor if you are allergic to any of these ingredients.**

## **What JEMPERLI looks like?**

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

## **Who distributes JEMPERLI?**

GlaxoSmithKline Australia Pty Ltd  
Level 4, 436 Johnston Street  
Abbotsford, Victoria, 3067 Australia

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