# Jemperli

# **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.

## 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 <u>1. What is Jemperli and what is it used for?</u> 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 <u>4. How will Jemperli be given to me?</u> in the full CMI.

#### 5. What should I know while using Jemperli?

Things you	Remind any doctor, dentist or pharmacist you visit that you are using Jemperli.		
should do	• Seek medical attention if you think you may be having an allergic reaction.		
	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.		
	<ul> <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>		
Things you	Do not stop using this medicine suddenly.		
should not do	It is very important that you do not miss a dose of this medicine.		
	Do not breast feed during treatment.		
Driving or using 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.		

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.

Active ingredient: Dostarlimab

# **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?
- 4. How will Jemperli be given to me?
- 5. What should I know while using Jemperli?
- 6. <u>Are there any side effects?</u>
- 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.

Jemperli is used in adults to treat a kind of cancer called endometrial cancer (cancer of the lining of the womb)

It is given when cancer has spread, or cannot be taken out by surgery, and has progressed on or following prior treatment.

Jemperli may be given in combination with other anticancer medicines. It is important that you also read the CMI for the other anticancer medicines you may be receiving. If you have any questions about these medicines, ask your doctor.

# 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 <u>6. Are there any side effects</u>?

#### 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.
- When 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 dosesthereafter.

When Jemperli is given in combination with chemotherapy, the recommended dose is 500 mg every 3 weeks for 6 doses, followed by 1000mg every 6 weeks for all doses thereafter as monotherapy treatment.

#### 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.

Ser	ious side effects	What to do
Inflammation of the lungs:		Call your doctor
•	shortness of breath chest pain new or worse cough (pneumonitis) <b>Jammation of the digestive tract</b> trouble swallowing decreased appetite burning in the chest (heartburn) chest or upper belly pain feeling sick (nausea), being sick (vomiting) diarrhoea, or more bowel movements than usual black, tarry, sticky stools; blood or mucus in stools severe stomach pain or	straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
Infl	ammation of the Liver:	
•	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	

•	bleeding or bruising more easily than normal	• diff obj	
Inflammation of the hormone glands:		• abr blo	
gia	nus.	• pai	n
٠	rapid heartbeat	• par	aly
•	weight loss or weight gain	• we	akn
•	increased sweating	Inflamn	nati
•	hair loss	(myeliti	
•	feeling cold	(inyent	57.
•	constipation	• pai	n
•	abdominal pain	• nur	mbr
•	deeper voice	• ting	glin
Ð	muscle aches	or l	-
•	dizziness or fainting	• bla	
•	headache that will not go away	inc	
	or unusual headache	mo	
Inf	lammation of the kidneys:	inc	
	changes in amount or colour of	Inflam	
_	urine	• cha	nge
•	swelling of the ankles		-
	loss of appetite blood in the urine	Inflamn	nat
	blood in the unne	• sev	ere
nf	lammation of the skin:	joir	וt p
	rash, itching, dry skin, peeling or	• sev	ere
-	skin sores	• swo	olle
	ulcers in the mouth, nose, throat	• fee	ling
	or genital area	Anaem	nia
	lammation of the heart muscle yocarditis):	<ul><li>sho</li><li>fee</li></ul>	
•	trouble breathing		
,	dizziness or fainting	Infusior	ז-re
,	fever	Some p	eoi
•	chest pain and chest tightness	reaction	-
•	flu like symptoms.	infusior	п. Т
nf	lammation of Brain and nervous	within ı	min
	tem (myasthenic	develop	շ սբ
syndrome/myasthenia gravis,		treatme	ent
Guillain-Barré syndrome,		Sympto	me
	cephalitis):		
•	neck stiffness	• sho	
•	headache	• itch	-
	fever, chills	• flus	
	vomiting	• diz:	
•	eye sensitivity to light	• chi	
•	weakness of eye muscles,	• fev	-
	drooping eyelids	• dro like	•
•	dry eyes and blurred vision		-
•	difficulty swallowing, dry mouth	Solid or	gar
	impaired speech	other c	
)	confusion and sleepiness	versus-	
,	dizziness	people	
,	pricking or pins and needles	marrow	-
	sensations in the hands and feet	uses do	no
		These c	

aching muscles

•	difficulty walking or lifting		
•	objects abnormal heartbeat/rate or		
	blood pressure		
•	pain paralysis in the extremities		
•	weakness		
	Inflammation of the 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		
Inf	ammation of the eye:		
•	changes in eyesight		
Infl	ammation of other organs:		
•	severe or persistent muscle or		
	joint pains		
•	severe muscle weakness swollen or cold hands or feet		
•	feeling tired		
An	aemia		
•	shortness of breath		
•	feeling tired		
Inf	usion-related reactions		
rea infi wit dev	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.		
Syr	nptoms include:		
•	shortness of breath or wheezing		
•	itching or rash flushing		
•	dizziness		
•	chills or shaking		
	fever drop in blood pressure (feeling		
	like passing out).		
oth ver peo	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.

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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 via <a href="https://pophealth.my.site.com/carmreportnz/s/">https://pophealth.my.site.com/carmreportnz/s/</a>.

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

Active ingredient (main ingredient)	Dostarlimab
Other ingredients (inactive ingredients)	sodium citrate, dihydrate; citric acid, monohydrate; arginine hydrochloride; sodium chloride; polysorbate 80; and water for injection

# 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.

Jemperli Dostarlimab 50 mg/mL solution for infusion TT50-11030

#### Who distributes Jemperli?

GlaxoSmithKline NZ Private Bag 106600 Downtown Auckland 1143 New Zealand

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