

# Participant Information Guide

This pamphlet is specifically designed for individuals participating in the SATELLITE clinical trial who are undergoing **dostarlimab** treatment.

Sponsor: The University of Queensland  
Ethics Approval Number: 104200



## Inside this pack you will find

This information guide – about treatment with **dostarlimab** and potential signs and symptoms (side effects) that you might experience, and what to do if you experience these.

A Participant Wallet Card – to alert healthcare professionals that you are on the SATELLITE TRIAL and receiving **dostarlimab**. The study doctor should complete the 'My Cancer Specialist's Contact Information' section of this Participant Wallet Card. **Always carry your study Participant Alert Card with you at all times.**

## Introduction

- The purpose of this guide is to give you important information about your treatment with **dostarlimab** and the potential **signs and symptoms (side effects)** you might experience.
- **Dostarlimab** is also known as *Jemperli*.
- It is important that you recognise the **signs and symptoms** of potential side effects from your **dostarlimab** treatment as they can be life threatening.
- If you experience signs or symptoms **call your study doctor or study coordinator immediately**. It is important you are treated as quickly as possible.
- If you cannot reach your study team, **go to your nearest emergency department** and advise them that you are a participant on an immunotherapy trial for cancer. This is a specific type of medication - it is not chemotherapy - advise them to call your study doctor.
- **Dostarlimab** can cause serious side effects which can be life threatening and lead to death. These side effects may happen at any time during treatment or even after your treatment has ended.
- This guide gives you instructions on what you should do if you experience any of these side effects.

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### PATIENT INFORMATION WEBSITE

Make sure you visit the **medsinfo.com.au** website where you will be able to access more information about your **dostarlimab** treatment. Side effects that may occur and what to do if you experience them.



# Participant study information

If I experience any signs or symptoms, I should contact the study doctor or study coordinator immediately.

**Participant Number:**

**Site:** \_\_\_\_\_  
Their contact number: \_\_\_\_\_

**Study doctor 1:** \_\_\_\_\_  
Contact number: \_\_\_\_\_  
After-hours contact number: \_\_\_\_\_

**Study doctor 2:** \_\_\_\_\_  
Contact number: \_\_\_\_\_  
After-hours contact number: \_\_\_\_\_

**Study nurse:** \_\_\_\_\_  
Contact number: \_\_\_\_\_

**In the case of emergency dial 000**  
**If you are on a mobile phone that has no network coverage dial 112**

# What is Dostarlimab?

**Dostarlimab** is an immunotherapy medication that works by helping your immune system fight your cancer. **Dostarlimab** is not chemotherapy. Treatment with **dostarlimab** may have side effects.

## Cancer and your immune system

Your immune system consists of many different cells that act as the body's natural defence system. These cells include white blood cells called 'T-cell'. T-cells can detect and destroy things like bacteria, viruses and cancer cells. Sometimes cancer cells find a way to hide from T-cells (for example, by blocking T-cell activity), almost as if they were wearing a cloak of invisibility. This can allow the cancer to grow and spread.

## How does dostarlimab work on cancer cells?

**Dostarlimab** is a medicine that helps by reactivating your immune system's T-cells so that they can detect cancer cells that are hiding. With **dostarlimab**, more active T-cells may be able to seek and attack cancer cells. This may mean that your cancer stops growing or spreading.

## What does treatment with dostarlimab involve?

**Dostarlimab** is infused directly into the bloodstream. You will receive the medication at a treatment centre, where you will have a needle placed into your vein, usually in your arm or the back of your hand. **Dostarlimab** will be slowly injected (infused) through this needle for about 30 minutes.

The dosing regimen comprising of 4 cycles every 3-weeks (Q3W), a rest period of 3-4 weeks followed by 3 cycles every 6 weeks (Q6W) for a total of 7 cycles.

It is important that you attend all your scheduled appointments, so your doctor can check your progress and administer **dostarlimab**. If you are unable to attend your appointment, call the study team immediately to reschedule your appointment.

Medical oncology consultation				Medical oncology consultation			
Rx		500mg Dorstarlimb IVI Q3W for 4 cycles		Rx		1000mg Dorstarlimb IVI Q6W for 3 cycles	
WK.1	WK.4	WK.7	WK.10	WK.12 3mths	WK.13	WK.19	WK.25
CYCLE 1	CYCLE 2	CYCLE 3	CYCLE 4		Cycle 5	CYCLE 6	CYCLE 7
 	 	 	 		 	 	 
							



## Keeping your medical team informed

It is important that you **advise the study team** before receiving **dostarlimab** if you:

- Have a disease of your immune system like Crohn's, ulcerative colitis or lupus.
- Have had an organ transplant (like a kidney transplant) or a bone marrow (stem cell transplant that used donor stem cells [allogeneic]).
- Have pneumonia or swelling of your lungs (called pneumonitis).
- Have liver damage.
- Are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarkets or health food shop.
- Are taking other medicines that make your immune system weak. Examples of these may include corticosteroids, such as prednisone.
- Are pregnant or intend to become pregnant. If you are a woman who could become pregnant, you must use effective contraception while you are being treated with **dostarlimab** for at least 4 months after your last dose.
- Are breastfeeding or intend to breastfeed. Do not breastfeed while taking **dostarlimab**.

## Possible side effects

Like all medicines, **dostarlimab** can cause side effects, although not everyone gets them. When you take **dostarlimab**, you can have some serious side effects. These side effects may happen at anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time. It is very important to tell the study doctor about any symptoms you notice while taking **dostarlimab**. The study doctor may give you other medicines in order to prevent more severe complications and reduce your symptoms. The study doctor may withhold the next dose of **dostarlimab** or stop your treatment with **dostarlimab** if your side effects are too severe.

## What to do if you have a side effect

**Call the study doctor straight away or go straight to the Emergency Department at your nearest hospital if you experience any signs or symptoms, or if they get worse.** Most mild to moderate immune-related side effects can be managed if detected early and treated, so it's important that you mention any new symptoms to study team right away.

- If you speak with another healthcare professional, show them your Participant Wallet Card.
- **DO NOT** treat any signs and symptoms yourself
- **DO NOT** feel embarrassed or worry that you are bothering the study team, they want to know early, so they can help you before the side effects become more serious.

## What to do if symptoms occur when you are away from home

**It is important that you contact the study doctor whenever symptoms occur.** Always carry your **dostarlimab** participant wallet card with the study team's contact information so that the team can be reached in case of an emergency. The participant wallet card contains important information about symptoms and side effects that need to be reported immediately to the study team. The participant wallet card also alerts other doctors that you are being treated on the SATELLITE study. Symptoms and side effects may happen at any time during treatment or even after your treatment has ended.

## Participant Wallet Card

- Always keep the participant wallet card with you as it contains important information about your cancer treatment.
- Show the participant wallet card to your GP, pharmacist or dentist etc. If you need to go a hospital emergency department, take this card with you.
- Keep this card with you even after you have completed your treatment because you may continue to experience side effects.

# Symptoms and side effects

SERIOUS SIDE EFFECTS	SIGNS OR SYMPTOMS
 <p><b>Lung problems</b> (Inflammation of the lungs)</p>	
 <p><b>Intestinal problems</b> (Inflammation of the intestines)</p>	
 <p><b>Liver problems</b> (Inflammation of the liver)</p>	
 <p><b>Kidney problems</b></p>	
 <p><b>Hormone gland problems</b> (especially the thyroid, pituitary and adrenal glands)</p>	
 <p><b>Blood sugar problems</b></p>	

# Symptoms and side effects

SERIOUS SIDE EFFECTS	SIGNS OR SYMPTOMS
 <p><b>Myocarditis</b> (Inflammation of the heart muscle)</p>	
 <p><b>Inflammation of the skin</b></p>	
 <p><b>Myelitis</b> (Inflammation of the spinal cord)</p>	
 <p><b>Myasthenia syndrome/ myasthenia gravis, Guillain Barre syndrome, encephalitis</b> (Inflammation of the brain and nervous system)</p>	
 <p><b>Inflammation of the eye</b></p>	
 <p><b>Inflammation of other organs</b></p>	



## Infusion-related reactions

Some people may have allergy like reactions when they receive an infusion. These reactions can occur within 24 hours after receiving an intravenous infusion, or can be delayed for up to about 2 weeks.

Call your study doctor straight away, or go straight to the emergency Department at your nearest hospital if you notice any of the following symptoms:

- Shortness of breath or wheezing
- Itching or rash
- Flushing
- Dizziness
- Chills or shaking
- Fever
- Drop in blood pressure (feeling like passing out)



















# Visit Schedule

	DATE	TIME
<b>Visit 1</b> Screening Visit	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Visit 2</b> Medical Oncology Review and Treatment Cycle 1	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Visit 3</b> Medical Oncology Review and Treatment Cycle 2	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Visit 4</b> Medical Oncology Review and Treatment Cycle 3	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Visit 5</b> Medical Oncology Review and Treatment Cycle 4	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Visit 6</b> Follow up (Gynaecological Clinical Review)	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Visit 7</b> Medical Oncology Review and Treatment Cycle 5	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Visit 8</b> Medical Oncology Review and Treatment Cycle 6	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Visit 9</b> Medical Oncology Review and Treatment Cycle 7	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Visit 10</b> Follow up (Gynaecological Clinical Review)	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Visit 11</b> Follow up (Gynaecological Clinical Review)	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Visit 12</b> Follow up (Gynaecological Clinical Review)	D   D   M   M   Y   Y   Y   Y	H   H   M   M
<b>Long term follow up (24 month)</b> Phone review – Fertility Outcome (if applicable)	D   D   M   M   Y   Y   Y   Y	H   H   M   M

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