

## 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.

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

### 1. Why am I using KAVIGALE?

KAVIGALE contains the active ingredient sipavibart. KAVIGALE is used to for the pre-exposure prophylaxis (prevention) of COVID-19 infection. It can be given to adults and adolescents aged 12 years and older weighing at least 40 kg who have a weakened immune system caused by a medical condition or by medicines or treatments.

For more information, see Section [1. Why am I using KAVIGALE?](#) in the full CMI.

### 2. What should I know before I use KAVIGALE?

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

Check with your doctor if you have low numbers of blood platelets (which help blood clotting), any blood clotting problems or are taking a medicine to prevent blood clots (an anticoagulant).

**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 use KAVIGALE?](#) in the full CMI.

### 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.

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

### 4. How is KAVIGALE given?

- The recommended dose is 300 milligrams (mg).
- KAVIGALE is given by your doctor or nurse as an injection into your muscle (usually the muscle of your thigh) or as an infusion into your vein. The infusion lasts about 6-20 minutes.

More instructions can be found in Section [4. How do I use KAVIGALE?](#) in the full CMI.

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any healthcare provider that you visit that you are using KAVIGALE.</li><li>• Contact your doctor right away if you get symptoms of COVID-19.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop being given KAVIGALE unless you have discussed it with your doctor first.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how KAVIGALE affects you. It is unlikely that KAVIGALE will affect your ability to drive or use machines.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Your healthcare provider is responsible for storing this medicine and disposing of any unused product correctly.</li></ul>

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

### 6. Are there any side effects?

All medicines can have side effects. If you do experience side effects, most of them are minor and temporary. However, some side effects may be serious and could require urgent medical attention or hospitalisation.

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).

# KAVIGALE®

Active ingredient(s): sipavibart

## Consumer Medicine Information (CMI)

This leaflet provides important information about using KAVIGALE. **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 KAVIGALE.**

Where to find information in this leaflet:

1. [Why am I using KAVIGALE?](#)
2. [What should I know before I use KAVIGALE?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use KAVIGALE?](#)
5. [What should I know while using KAVIGALE?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using KAVIGALE?

**KAVIGALE contains the active ingredient sipavibart.**

Sipavibart is a type of protein called a monoclonal antibody. KAVIGALE is a passive immunisation that works specifically against the SARS-CoV-2 virus by preventing it from entering human cells. This can help prevent you from getting COVID-19 illness.

**KAVIGALE is used for the pre-exposure prophylaxis (prevention) of COVID 19 infection. It can be given to adults and adolescents aged 12 years and older weighing at least 40 kg who have a weakened immune system caused by a medical condition, or by medicines or treatments.**

KAVIGALE is not recommended as a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended.

## 2. What should I know before I use KAVIGALE?

### Warnings

**Do not use KAVIGALE if:**

- You are allergic to sipavibart, 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 allergies
- have low numbers of blood platelets (which help blood clotting)
- any blood clotting problems or are taking a medicine to prevent blood clots (an anticoagulant)
- have any other medical conditions

- are taking, have recently taken or might 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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare provider for advice before receiving this medicine.

Tell your doctor if you are pregnant, or if you might be pregnant. There is not enough information to be sure that KAVIGALE is safe for use in pregnancy. KAVIGALE will only be given if the potential benefits of treatment outweigh the potential risks to the mother and the unborn child.

Talk to your doctor if you are breastfeeding or intend to breastfeed. This is because it is not yet known whether KAVIGALE passes into human breast milk, or what the effects might be on the baby or milk production. Your doctor will help you decide whether to keep breast feeding or to start treatment with this medicine.

### Children and adolescents

KAVIGALE should not be given to children under 12 years of age or weighing less than 40 kg.

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

If you are getting a COVID-19 vaccine, tell your doctor, nurse or pharmacist that you have used or are using KAVIGALE.

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. This is because it is not yet known if this medicine affects other medicines, or if it is affected by them.

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

## 4. How is KAVIGALE given?

### How much KAVIGALE is given

- The recommended dose for the prevention of COVID-19 is 300 milligrams (mg).
- For continuous prevention of COVID-19 you may need to receive repeat doses of 300 mg KAVIGALE every 3 months.

## How will you be given KAVIGALE

- KAVIGALE is given by your healthcare provider as an injection into your muscle (usually the muscle of your thigh) or as an infusion into your vein. The infusion lasts about 6-20 minutes.
- Your doctor or nurse will decide how long you will be monitored after you are given the medicine. This is in case you have side effects.

## If you use too much KAVIGALE

As KAVIGALE is given under the close supervision of a healthcare provider it is unlikely that you will be given too much. If you are concerned that you have been given too much KAVIGALE, tell your healthcare provider immediately, phone the Poisons Information Centre (by calling 13 11 26) or go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

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

### Things you should do

Tell any other doctors you see that you have had this medicine to prevent COVID-19.

If you are getting a COVID-19 vaccine, tell the doctor, nurse or pharmacist you have had this medicine.

COVID-19 is caused by different strains (variants) of the SARS-CoV-2 virus that change over time. KAVIGALE may be less effective at preventing COVID-19 caused by some strains than others.

Contact your doctor right away if you get symptoms of COVID-19. COVID-19 affects different people in different ways:

- the most common symptoms include fever, chills, sore throat, cough, tiredness and loss of taste or smell;
- the most serious symptoms include difficulty breathing or shortness of breath, loss of speech or mobility, or confusion and chest pain.

### Call your doctor straight away if you:

- notice any signs of a cardiac event, such as:
  - o chest pain
  - o shortness of breath
  - o a general feeling of discomfort, illness, or lack of well-being
  - o feeling lightheaded or faint
- notice any signs of an allergic reaction, such as:
  - o difficulty breathing or swallowing
  - o swelling of the face, lips, tongue or throat
  - o severe itching of the skin, with a red rash or raised bumps.
- notice any signs of a reaction to the infusion. This could happen immediately or within a few hours of the infusion. Symptoms may include:

- o fever and chills
- o feeling tired or weak
- o feeling sick (nausea) or vomiting
- o fast heart rate
- o chest pain or discomfort
- o muscle aches
- o feeling lightheaded or faint.

### Driving or using machines

It is unlikely that KAVIGALE will affect your ability to drive or use machines.

### Looking after your medicine

Your healthcare provider is responsible for storing this medicine and disposing of any unused product correctly. The following information is intended for healthcare professionals.

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.

Unopened vials:

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

Prepared syringes or prepared infusion bags should be used immediately. If necessary, store the prepared syringes or prepared infusion bags for no more than either:

- 24 hours at 2°C to 8°C, or
- 4 hours at room temperature up to 25°C.

### Keep it where young children cannot reach it.

### Getting rid of any unwanted medicine

Unused medicine or waste material 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.

Patients receiving medicines similar to KAVIGALE have experienced some serious allergic reactions. See Section [5. What should I know while using KAVIGALE?](#) and the serious side effects table below for the signs of an allergic reaction.

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

## Less serious side effects

Less serious side effects	What to do
<p><b>Injection site related reactions (near where the injection in the muscle was given).</b></p> <p>These can happen within 7 days of the injection and resolve within a few days. Symptoms may include:</p> <ul style="list-style-type: none"><li>• bruising</li><li>• pain</li><li>• itching</li><li>• redness</li><li>• swelling</li><li>• blood under the skin</li><li>• numbness and tingling</li><li>• rash</li><li>• discolouration</li><li>• warm feeling on the skin</li><li>• discomfort</li><li>• inflammation</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>
<p><b>Infusion site related reactions (near where the infusion in the vein was given).</b></p> <p>These can happen within 7 days of the infusion and resolve within a few days. Symptoms may include:</p> <ul style="list-style-type: none"><li>• bruising</li><li>• pain</li><li>• itching</li><li>• redness</li><li>• swelling.</li></ul>	
<p><b>Reactions to the infusion.</b></p> <p>These can happen at the time of infusion or within a few hours, and usually on the same day. Symptoms usually resolve within a few days and signs of a reaction to the infusion may include:</p> <ul style="list-style-type: none"><li>• fever and chills</li><li>• tiredness or weakness</li><li>• nausea or vomiting</li><li>• fast heart rate</li><li>• chest pain or discomfort</li><li>• muscle aches</li><li>• joint pain</li><li>• feeling light headed or faint.</li><li>• headache</li><li>• upset stomach</li><li>• pain</li></ul>	

## Serious side effects

Serious side effects	What to do
<p><b>Serious allergic reactions</b></p> <p>These can happen within 14 days of the injection and resolve within a few days. Symptoms may include:</p> <ul style="list-style-type: none"><li>• difficulty breathing or swallowing</li><li>• swelling of the face, lips, tongue or throat</li><li>• severe itching of the skin, with a red rash, raised bumps or hives, feeling lightheaded or faint</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>

**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 KAVIGALE contains

<b>Active ingredient (main ingredient)</b>	sipavibart
<b>Other ingredients (inactive ingredients)</b>	histidine, histidine hydrochloride monohydrate, arginine hydrochloride, polysorbate 80 and water for injections

**Do not use this medicine if you are allergic to any of these ingredients.**

### What KAVIGALE looks like

KAVIGALE is a clear to opalescent, colourless to slightly yellow solution provided in a clear glass vial with a light green cap.

The vial contains 300 mg of sipavibart in 2 mL.

Each pack contains 1 vial.

(AUST R 459773).

### Who distributes KAVIGALE

AstraZeneca Pty Ltd  
ABN 54 009 682 311

66 Talavera Road  
MACQUARIE PARK NSW 2113  
Telephone:- 1800 805 342

This leaflet was prepared in November 2025.

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