Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrKAVIGALE™
Sipavibart injection

This Patient Medication Information is written for the person who will be taking **KAVIGALE.** This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **KAVIGALE**, talk to a healthcare professional.

What KAVIGALE is used for:
KAVIGALE is used:
- For the pre-exposure prophylaxis (prevention) of COVID-19 infection. It can be given to adults and adolescents 12 years of age and older weighing at least 40 kg who:
    - have a weakened immune system caused by a medical condition or by medicines or treatments
    - or those who cannot receive a COVID-19 vaccine.

How KAVIGALE works:
KAVIGALE contains the active substance sipavibart. Sipavibart is a type of protein called a monoclonal antibody. KAVIGALE is a passive immunization 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.

The ingredients in KAVIGALE are:
Medicinal ingredient: Sipavibart
Non-medicinal ingredients: L-Histidine, L-Histidine hydrochloride monohydrate, L-Arginine hydrochloride, Polysorbate 80, Water for Injection.

KAVIGALE comes in the following dosage forms:
KAVIGALE is supplied as a single-dose vial. KAVIGALE is preservative-free. Each carton of KAVIGALE contains one vial of 300 mg sipavibart in 2 mL (150 mg/mL) Solution for injection/Solution for infusion.

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

Do not use KAVIGALE if:
- you are allergic to sipavibart or any of the other ingredients of this medicine (see The ingredients in KAVIGALE are).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take KAVIGALE. Talk about any health conditions or problems you may have, including if you:

- have had a heart attack or stroke, have other heart problems, or are at high-risk of cardiac (heart) events.
- 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 ever had an allergic reaction after you were given KAVIGALE in the past.
- are pregnant, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before receiving this medicine. 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 use outweigh the potential risks to you and your unborn child.
- are breast-feeding, ask your healthcare professional for advice before receiving this medicine. It is unknown if KAVIGALE or the COVID-19 virus pass into human breast milk. You will need to consider the potential benefits of use for you, compared with the health benefits and risks of breast-feeding for your baby.

Cardiac event
Tell your healthcare professional or seek medical help right away if you notice any signs of a cardiac event following administration of KAVIGALE such as: chest pain, shortness of breath, a general feeling of discomfort, illness or lack of well-being, feeling lightheaded or faint.

Allergic reaction
Tell your healthcare professional or seek medical help right away if you notice any signs of allergic reaction during or following administration of KAVIGALE such as: difficulty breathing or swallowing, swelling of the face, lips, tongue or throat, severe itching of the skin, with a red rash or raised bumps.

Reaction to the infusion
Tell your healthcare professional or seek medical help right away if you notice any signs of reaction to the infusion immediately or within a few hours of the infusion including fever and chills, tiredness or weakness, nausea or vomiting, fast heart rate, chest pain or discomfort, muscle aches, feeling lightheaded or faint.

Other warnings you should know about:
KAVIGALE should not be given to children below 12 years of age or weighing less than 40 kg.

COVID-19 is caused by different variants of the SARS-CoV-2 virus that change over time. KAVIGALE may be less effective at preventing COVID-19 caused by some variants than others. **KAVIGALE is not expected to be effective against KP.2 and KP.3 variants.** Contact your healthcare professional 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 new 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.

Driving and Using Machines:
It is unlikely that KAVIGALE will affect your ability to drive or use machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

No drug interaction studies have been conducted with KAVIGALE.

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

Usual dose:
The recommended dose for the prevention of COVID-19 is 300 mg.

For continuous prevention of COVID-19 you may need to receive repeat doses of 300 mg KAVIGALE every 6 months.

Overdose:

If you think you, or a person you are caring for, have taken too much KAVIGALE, contact a healthcare professional, hospital emergency department, or regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7996) immediately, even if there are no signs or symptoms.

Missed dose:
If a dose of KAVIGALE is missed contact your healthcare professional as soon as possible.

Possible side effects from using KAVIGALE:
These are not all the possible side effects you may have when taking KAVIGALE. If you experience any side effects not listed here, tell your healthcare professional.

Patients receiving medicines similar to KAVIGALE have experienced some serious allergic reactions. See **Allergic reaction** above for the signs of an allergic reaction.

Common (may affect up to 1 in 10 people)
- Injection site reactions (near where the injection in the muscle was given). These can happen within 7 days of the injection and resolve within a few days. Symptoms are mild and may include: pain, bruising, redness, bleeding, swelling, blood under the skin, itching, numbness and tingling, rash, discolouration, warm feeling on the skin, discomfort, inflammation.
- Allergic (hypersensitivity) reactions. These can happen within 14 days of the injection and resolve within a few days. Symptoms are mild to moderate and may include: itching, redness, hives, rash, feeling lightheaded or faint.
- Infusion site reactions (near where the infusion in the vein was given). These can happen within 7 days of the infusion and resolve within a few days. Symptoms are mild to moderate and may include: bruising, pain, itching, redness, swelling.
- Reactions to the infusion. These can happen at the time of infusion or within a few hours, and usually on the same day. Symptoms are mild, usually resolve within a few days and may include: nausea, joint pain, headache, fever, chills, upset stomach, pain, feeling lightheaded or faint.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough

to interfere with your daily activities, tell your healthcare professional.

Reporting side effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

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

- Keep out of reach and sight of children.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Store the unopened vials 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:
  - 24 hours at 2°C to 8°C, and
  - 4 hours at room temperature up to 25°C.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

If you want more information about KAVIGALE:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website: www.astrazeneca.ca, or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at www.astrazeneca.ca.

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