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Kavigale (*sipavibart*)

An overview of Kavigale and why it is authorised in the EU

What is Kavigale and what is it used for?

Kavigale is a medicine used to prevent COVID-19 in people aged 12 years and older who weigh at least 40 kilograms. It is used in people who are immunocompromised (have a weakened immune system) due to a medical condition or because they are using medicines that suppress the immune system (immunosuppressants).

Kavigale contains the active substance sipavibart.

The medicine should be used in accordance with official recommendations where available and based on information on the activity of sipavibart against circulating viral variants.

How is Kavigale used?

Kavigale can only be obtained with a prescription and must be given by a healthcare professional in a healthcare facility where patients can be adequately monitored and managed in case they develop severe allergic reactions, including anaphylaxis.

Kavigale is given as a single injection into the thigh muscle or infusion (drip) into a vein.

For more information about using Kavigale, see the package leaflet or contact your doctor or pharmacist.

How does Kavigale work?

Kavigale contains sipavibart, a monoclonal antibody (a type of protein) that has been designed to recognise and attach to the spike protein of SARS-CoV-2, the virus that causes COVID-19. SARS-CoV-2 uses this protein to enter the body's cells. When sipavibart attaches to the spike protein, it prevents the virus from entering the cell and multiplying.

Sipavibart may not be active against all circulating virus variants.

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What benefits of Kavigale have been shown in studies?

A main study involved over 3,300 adults and adolescents over 12 who were immunocompromised. The results showed that 2 doses of Kavigale given 6 months apart reduced the risk of symptomatic COVID-19 infection in the 6 months after the last dose by around 30%. People received Kavigale or either placebo (a dummy injection) or another COVID-19 monoclonal antibody (Evusheld) that was no longer active against the virus variants circulating at the time of the study. Of the people given Kavigale, 9.2% (151 out of 1,649) got COVID-19 symptoms, compared with 12.7% (207 out of 1,631) of people who received either placebo or the comparator monoclonal antibody.

After the main study data were collected, new variants of the virus emerged, including those with a mutation (genetic change) in the spike protein called F456L. Laboratory studies showed that sipavibart cannot neutralise viruses with this mutation. It is therefore not expected to be effective at preventing COVID-19 caused by these variants.

Further analyses of the data from the main study showed that Kavigale reduces the risk of symptomatic COVID-19 caused by viruses that do not carry the F456L mutation by around 35%.

What are the risks associated with Kavigale?

For the full list of side effects and restrictions with Kavigale, see the package leaflet.

When Kavigale is given as an injection into the muscle, the most common side effects (which may affect up to 1 in 10 people) include reactions at the site of injection, such as pain, bruising, redness or swelling. When given as an infusion into a vein, the most common side effects include reactions at the site of infusion (such as bruising, pain, itching or redness) and reactions related to the infusion (such as nausea, joint pain, headache or fever).

Why is Kavigale authorised in the EU?

At the time of approval, there was an unmet need for medicines to prevent COVID-19 in people who are immunocompromised and may therefore have a lower response to vaccination. In these people, Kavigale was shown to be effective at preventing symptomatic COVID-19 caused by SARS-CoV-2 variants circulating at the time of the study. The safety profile of Kavigale is favourable and side effects are generally mild.

The European Medicines Agency therefore decided that Kavigale’s benefits are greater than its risks when used against susceptible virus variants and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Kavigale?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Kavigale have been included in the summary of product characteristics and the package leaflet. These include information for healthcare professionals to inform them that Kavigale is not effective against virus variants with the F456L mutation and to remind them to check their national recommendations before using the medicine.

As for all medicines, data on the use of Kavigale are continuously monitored. Suspected side effects reported with Kavigale are carefully evaluated and any necessary action taken to protect patients.

Other information about Kavigale

Kavigale received a marketing authorisation valid throughout the EU on 20 January 2025.

Further information on Kavigale can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/kavigale.

This overview was last updated in 01-2025.