12 December 2024
EMA/CHMP/562567/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kavigale

sipavibart

On 12 December 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Kavigale, intended for the prevention of COVID-19 in immunocompromised people aged 12 years and older.

Kavigale was reviewed under EMA's accelerated assessment programme.

The applicant for this medicinal product is AstraZeneca AB.

Kavigale will be available as 300 mg solution for injection and infusion. The active substance of Kavigale is sipavibart, an immunoglobulin, antiviral monoclonal antibody (ATC code: J06BD09). Sipavibart is a recombinant human IgG1 monoclonal antibody that provides passive immunisation against SARS-CoV 2 by binding its spike protein receptor binding domain.

The benefit of Kavigale is a reduction in the risk of developing symptomatic COVID-19 due to any SARS-CoV-2 variant compared to comparator (either tixagevimab plus cilgavimab or placebo), in immunocompromised people aged 12 years and older. The reduction was greater for disease attributed to matched (non-F456L mutation containing) SARS-CoV-2 variants.

The most common side effects with Kavigale are injection site reaction when given as intramuscular injection, and infusion site and related reactions when given by intravenous infusion.

The full indication is:

> KAVIGALE is indicated for the pre-exposure prophylaxis of COVID-19 in adults and adolescents 12 years of age and older weighing at least 40 kg and who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments.
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> KAVIGALE should be used in accordance with official recommendations where available and based on information on the activity of sipavibart against presently circulating viral variants (see sections 4.4 and 5.1).

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

KAVIGALE must be administered by a healthcare professional.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.