9 October 2026
EMA/CVMP/192960/2026
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Stemyca

Common name: equine umbilical cord mesenchymal stem cells

On 8 October 2026, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Stemyca, a concentrate for dispersion for infusion, intended for dogs. The applicant for this veterinary medicinal product is EquiCord S.L.

Stemyca is an intestinal anti-inflammatory veterinary medicinal product containing equine umbilical cord mesenchymal stem cells (EUC-MSCs) (ATCvet code not yet available) as the active substance, which are thought to act via prostaglandin secretion, as well as their immunomodulatory and anti-inflammatory properties. These properties have been demonstrated in proprietary *in vitro* studies.

The benefit of Stemyca is its efficacy in the indication 'reduction of clinical signs of non-food-responsive chronic inflammatory enteropathy (CIE) in dogs'. Stemyca will thus provide a new treatment possibility for the reduction of clinical signs for this disease in dogs.

There were no adverse events detected in dogs. Stemyca is generally well tolerated at the recommended dose. No adverse reactions were observed in an exploratory study with a double dose conducted in dogs.

The full indication is: "Reduction of clinical signs of non-food-responsive chronic inflammatory enteropathy (CIE) in dogs".

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), which will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Stemyca and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt 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

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