17 June 2022
EMA/CVMP/576246/2022
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

DogStem

International non-proprietary name (INN): equine umbilical cord-derived mesenchymal stem cells

On 15 June 2022, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product DogStem, suspension for injection, intended for dogs. The applicant for this veterinary medicinal product is EquiCord S.L.

DogStem is a biological veterinary medicinal product containing equine umbilical cord-derived mesenchymal stem cells as the active substance. The product aims to reduce pain and lameness associated with osteoarthritis in dogs, through immunomodulatory and anti-inflammatory properties attributed to their paracrine activity.

The benefits of DogStem are its effects on reduction of pain and lameness associated with osteoarthritis in dogs.

The most common side effects are injection site reactions such as lameness and pain during the first week after administration and other mild site reactions such as limb swelling and heat during the first day after administration.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) 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 DogStem and therefore recommends the granting of the marketing authorisation.

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

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