EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 February 2022
EMA/CVMP/73401/2022
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

RenuTend

Tenogenic primed equine allogeneic peripheral blood-derived mesenchymal stem cells

On 16 February 2022, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product RenuTend, suspension for injection, intended for horses. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

RenuTend is a biological veterinary medicinal product containing tenogenic primed equine allogeneic peripheral blood-derived mesenchymal stem cells as the active substance. The product aims to promote tissue restoring and healing mechanisms in tendons and ligaments, such as improving extracellular matrix production.

The benefits of RenuTend are its effects on improving healing of injuries of tendons and suspensory ligaments in horses.

The most common side effects are mild injection site reactions, such as increased heat, pain at palpation, limb swelling and increased limb circumference during the first 10 days after administration.

Detailed conditions for the use of this product are 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 RenuTend 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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