16 March 2018
EMA/CVMP/25787/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Semintra

International non-proprietary name (INN): telmisartan

On 15 March 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Semintra. The marketing authorisation holder for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Semintra is currently authorised as a 4 mg/ml oral solution for cats for the reduction of proteinuria associated with chronic kidney disease. The extension concerns the addition of a new strength, Semintra 10 mg/ml oral solution for cats, for the following indication: "Treatment of systemic hypertension in cats."

The most common adverse reactions are mild and transient gastrointestinal signs, such as vomiting and diarrhoea.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the extension to 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 Semintra and therefore recommends the granting of the extension to 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.

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