18 March 2016
EMA/CVMP/186144/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Bravecto

International non-proprietary name (INN): fluralaner

On 17 March 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive final opinion, recommending the granting of an extension to the marketing authorisation for the veterinary medicinal product Bravecto further to a re-examination of the initial negative opinion adopted by CVMP on 9 December 2015. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

Bravecto is currently authorised as chewable tablets for dogs. The extension concerns the addition of a new pharmaceutical form (spot-on solution) and of a new target species (cats) for this spot-on formulation. The product will be available in pipettes containing spot-on solution of 112.5 mg, 250 mg, 500 mg, 1000 mg and 1400 mg for dogs, and 112.5 mg, 250 mg and 500 mg for cats.

Bravecto spot-on solution is intended for the treatment of tick and flea infestations in both dogs and cats. The most common adverse reactions in dogs are mild and transient skin reactions such as erythema or alopecia at the application site and also pruritus at the application in cats.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), for which an updated version 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 Bravecto spot-on solution for dogs and cats and therefore recommends the granting of the extension to the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision.

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