16 March 2018
EMA/CVMP/35302/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Bravecto Plus

International non-proprietary name (INN): fluralaner / moxidectin

On 15 March 2018, 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 Bravecto Plus spot-on solution intended for the treatment of tick and flea infestations, for the prevention of heartworm disease caused by *Dirofilaria immitis*, and for the treatment of infections with intestinal roundworm and hookworm in cats. The applicant for this veterinary medicinal product is Intervet International B.V.

Bravecto Plus is an antiparasitic medicinal product containing fluralaner / moxidectin (ATCvet code QP54AB52) as active substances. Fluralaner is an ectoparasiticide belonging to the isoxazoline group, which is systemically active against ticks and fleas. Moxidectin belongs to the milbemycin group of macrocyclic lactones and has parasiticidal activity against a range of internal and external parasites including various nematode species.

The benefits of Bravecto Plus are its effective use in the treatment of tick and flea infestations, prevention of heartworm disease, and treatment of infections with intestinal roundworm and hookworm in cats. The most common side effects are mild and transient skin reactions at the application site.

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 Bravecto Plus 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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