8 November 2019
EMA/CVMP/599149/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Bravecto Plus

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

On 7 November 2019, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Bravecto Plus. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

Bravecto Plus is currently authorised as spot-on solution for cats with, or at risk from, mixed parasitic infestations by ticks or fleas and ear mites, gastrointestinal nematodes or heartworm. The variation concerns the modification of the approved therapeutic indication for the prevention of heartworm disease caused by *Dirofilaria immitis*, i.e. to extend the duration of prevention from 8 weeks to 12 weeks.

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 variation to the marketing authorisation has been granted by the European Commission.

[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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