EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2013
EMA/CVMP/627638/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Bravecto

International non-proprietary name (INN): Fluralaner

On 12 December 2013, 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 chewable tablets for dogs (112.5 mg, 250 mg, 500 mg, 1000 mg, 1400 mg). The applicant for this veterinary medicinal product is Intervet International B.V..

The active substance of Bravecto is fluralaner, a new ectoparasiticide belonging to the isoxazoline group, which is systemically active against ticks and fleas. The benefit of Bravecto is its efficacy in the treatment of flea and tick infestations in dogs. The most common side effects are mild and transient gastrointestinal effects.

The recommended indication is:
For the treatment of tick and flea infestations in dogs. This veterinary medicinal product is a systemic insecticide and acaricide that provides
- immediate and persistent flea killing activity for 12 weeks (*Ctenocephalides felis*),
- immediate and persistent tick killing activity for 12 weeks (*Ixodes ricinus, Dermacentor reticulatus* and *Dermacentor variabilis);*
- immediate and persistent tick killing activity for 8 weeks (*Rhipicephalus sanguineus*).
Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance. The onset of effect is within 8 hours of attachment for fleas (*C. felis*) and 12 hours of attachment for ticks (*I. ricinus*).
The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

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 to risk balance for Bravecto 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 within 90 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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