EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 October 2017
EMA/CVMP/618926/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

MiPet Easecto

International non-proprietary name (INN): sarolaner

On 5 October 2017, 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 MiPet Easecto chewable tablets for dogs, intended for treatment of tick infestations, flea infestations, sarcoptic mange, ear mite infestations, and demodicosis. The applicant for this veterinary medicinal product is Zoetis Belgium SA.

MiPet Easecto is an ectoparasiticide for systemic use containing sarolaner (ATCvet code QP53BE03) as active substance, which blocks GABA- and glutamate-gated chloride channels in the central nervous system of insects and acarines.

The benefits of MiPet Easecto are its efficacy in the treatment of ectoparasite infestations in dogs as follows: tick infestations (*Dermacentor reticulatus*, *Ixodes hexagonus*, *Ixodes ricinus* and *Rhipicephalus sanguineus*), flea infestations (*Ctenocephalides felis* and *Ctenocephalides canis*), and mite infestations (*Demodex canis*, *Otodectes cynotis* and *Sarcoptes scabiei*). The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD). In very rare cases, adverse reactions associated with mild and transient gastrointestinal effects such as vomiting and diarrhoea may occur as well as transient neurological disorders such as tremor, ataxia or convulsion. These signs typically resolve without treatment.

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 MiPet Easecto 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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