7 October 2022
EMA/CVMP/780812/2022
Committee for Veterinary Medicinal Products

Summary of opinion[1] (post-authorisation)

Simparica; MiPet Easecto

International non-proprietary name (INN): sarolaner

On 6 October 2022, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal products Simparica and MiPet Easecto. The marketing authorisation holder (MAH) for these veterinary medicinal products is Zoetis Belgium SA.

Simparica and MiPet Easecto are currently authorised as chewable tablets for use in dogs for the treatment of tick and flea infestations and for the treatment of sarcoptic mange, ear mite infestations and demodicosis. This variation concerns the addition of a new therapeutic indication for reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for 28 days after treatment. The MAH also takes the opportunity to update the product information for MiPet Easecto following a PSUR recommendation.

Detailed conditions for the use of these products are described in the 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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