9 December 2022
EMA/CVMP/904196/2022
Committee for Veterinary Medicinal Products

Summary of opinion[1] (post-authorisation)

Simparica Trio

International non-proprietary name (INN): sarolaner / moxidectin / pyrantel embonate

On 8 December 2022, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a group of variations to the terms of the marketing authorisation for the veterinary medicinal product Simparica Trio. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

Simparica Trio is currently authorised as chewable tablets for use in dogs. The group of variations concerns the addition of three new therapeutic indications: for the treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*), for the treatment of demodicosis (caused by *Demodex canis*), and for the prevention of establishment of thelaziosis (adult *Thelazia callipaeda* eyeworm infection).

Detailed conditions for the use of this product 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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