8 September 2017
EMA/CVMP/557544/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Simparica

International non-proprietary name (INN): sarolaner

On 7 September 2017, 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 Simparica. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

Simparica is currently authorised as chewable tablet. The changes concern the addition of new indications for the treatment of ear mites and demodicosis in dogs.

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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

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