21 June 2024
EMA/CVMP/95671/2024
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Rabitec

Common name: Rabies vaccine (live, oral) for foxes, raccoon dogs and dogs

On 19 June 2024, 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 product Rabitec. The marketing authorisation holder for this veterinary medicinal product is CEVA Santé Animale

Rabitec is currently authorised as oral suspension. The variation concerns to add:

- a new a strength (infectivity titre) including a new target species (dogs)
- a new composition of the bait (for the new target species dogs)
- a new vaccine container (sachet - for the new target species 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 Union Product Database (UPD) 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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