EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 January 2020
EMA/CVMP/691934/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Rabitec

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

On 23 January 2020, 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 Rabitec. The marketing authorisation holder for this veterinary medicinal product is IDT Biologika GmbH.

Rabitec is currently authorised as an oral suspension for the active immunization of foxes and raccoon dogs against rabies to prevent infection and mortality. The variation concerns extending the duration of immunity of the product from 6 to 12 months.

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.

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