22 March 2019
EMA/CVMP/147691/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

ProZinc

International non-proprietary name (INN): insulin human

On 21 March 2019, 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 ProZinc. The marketing authorisation holder for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

ProZinc is currently authorised as suspension for injection for the treatment of diabetes mellitus in cats to achieve reduction of hyperglycaemia and improvement of associated clinical signs. The variation concerns the addition of a new non-food producing target species (dogs) for the same indication.

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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