17 May 2013
EMA/CVMP/250455/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

ProZinc

International non-proprietary name (INN): Insulin human

On 16 May 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product ProZinc, 40 IU/ml, suspension for injection, intended for the treatment of diabetes mellitus in cats to achieve reduction of hyperglycaemia and improvement of associated clinical signs. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

The active substance of ProZinc is human insulin derived by recombinant DNA technology in a protamine zinc suspension. Human insulin (rDNA) (ATC vet code QA10A) is a hormone structurally identical to endogenous human insulin which regulates glucose metabolism by binding to insulin receptors on muscle and fat cells and increases the cellular uptake of glucose. The main effect of insulin is the reduction in circulating blood glucose concentrations. Protamine zinc human insulin (rDNA) exhibits a delayed absorption and onset of action due to the addition of protamine and zinc leading to crystal formation.

The benefits of ProZinc are the reduction of hyperglycaemia and associated clinical signs in diabetic cats, with the majority of treated cats experiencing an improvement in glycaemic control. The most common side effect is hypoglycaemia associated with clinical signs which may include hunger, anxiety, unstable locomotion, muscle twitching, stumbling or sinking in the rear legs and disorientation.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[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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The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for ProZinc and therefore recommends the granting of the marketing authorisation.