9 November 2018
EMA/CVMP/719848/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Isemid

International non-proprietary name (INN): torasemide

On 8 November 2018, 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 Isemid, chewable tablets, intended for treatment of clinical signs related to congestive heart failure in dogs, including pulmonary oedema. The applicant for this veterinary medicinal product is CEVA Santé Animale.

Isemid is a loop diuretic medicinal product containing torasemide (ATCvet code QC03CA04) as active substance, which acts in the loop of Henle to inhibit reabsorption of sodium and chloride, thus increasing the excretion of these ions and thus increasing the volume of water excreted in urine.

The benefits of Isemid are its efficacy in the treatment of clinical signs related to congestive heart failure in dogs, including pulmonary oedema. The most common side effects are renal insufficiency, an increase in renal blood parameters, haemoconcentration and alterations in electrolyte levels.

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.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Isemid and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 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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