EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 July 2025
EMA/CVMP/223195/2025
Committee or Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Hemosyvet

International non-proprietary name (INN): Etamsylate

On 17 July 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Hemosyvet, solution for injection, intended for cats, cattle, dogs, goats, horses, pigs and sheep. The applicant for this veterinary medicinal product is Axience. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Hemosyvet is an haemostatic and angio-protective medicinal product containing etamsylate (ATCvet code QB02 BX01) as the active substance which stimulates platelet adhesiveness, shortening bleeding time, and rapidly and lastingly normalizes the altered vascular fragility and permeability.

Hemosyvet is a generic of HEMO 125 mg/ml solución inyectable, which has been authorised in the EU since July 1992. Studies have demonstrated the satisfactory quality of Hemosyvet, and its bioequivalence to the reference product HEMO 125 mg/ml solución inyectable.

The full indication is: prevention and treatment of surgical, post traumatic, obstetric and gynaecological haemorrhages.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) 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 Hemosyvet and therefore recommends the granting of the marketing authorisation.

[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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