8 September 2023
EMA/CVMP/374571/2023
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Oxmax

International non-proprietary name (INN): hemoglobin betafumaril (bovine)

On 7 September 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Oxmax 65 mg/ml solution for infusion for dogs. The applicant for this veterinary medicinal product is New Alpha Innovation Biopharmaceutical Ireland Limited. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Oxmax is blood substitute containing hemoglobin betafumaril (bovine) (ATCvet code QB05AA91) as active substance, which is acting as oxygen-carrier with physical and chemical properties similar to that of haemoglobin contained within red blood cells.

The benefits of Oxmax are its efficacy as an adjunct therapy in the management of canine haemorrhagic shock. A beneficial effect of treatment was demonstrated for 24 hour survival rate when Oxmax was administered concomitantly with low dose resuscitative fluids (Lactated Ringer's solution).

The most common side effects are gastrointestinal signs (diarrhoea, abnormal stool colouration, blood in faeces; vomiting), shivering, sneezing, and reactions at the site of infusion (site reddening and swelling).

The appropriate CVMP guidelines on data requirements for veterinary medicinal products intended for minor use or minor species/limited markets have been applied in the assessment of the application.

Detailed conditions for the use of this product will be 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.

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