5 December 2025
EMA/CVMP/367341/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Varenzin

International non-proprietary name (INN): Molidustat

On 4 December 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 Varenzin, oral suspension, intended for cats. The applicant for this veterinary medicinal product is Elanco GmbH.

Varenzin is a medicinal product containing molidustat (as molidustat sodium) as the active substance (ATCvet code: QB03XA09). Molidustat is an antianemic preparation which is a competitive and reversible inhibitor of hypoxia-inducible factor prolyl hydroxylase (HIF-PH). The inhibition of HIF-PH induces a dose-dependent increase of endogenous erythropoietin (EPO) by stabilising HIF, resulting in increased erythropoiesis.

The benefit of Varenzin is the management of non-regenerative anaemia associated with chronic kidney disease (CKD) in cats, by increasing haematocrit/ packed cell volume.

The most common side effect is vomiting.

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 Varenzin 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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