14 February 2025
EMA/27689/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Omeprazole TriviumVet

International non-proprietary name (INN): Omeprazole

On 12 February 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 Omeprazole TriviumVet, gastro-resistant capsule, hard, intended for dogs. The applicant for this veterinary medicinal product is TriviumVet DAC. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Omeprazole TriviumVet contains omeprazole as active substance (QA02BC01). Omeprazole is a proton pump inhibitor (PPI), it inhibits the H+/K+ proton pump at the luminal surface of the parietal cell that secretes hydrogen ions into the gastric lumen, thus decreasing gastric acid secretion. Reducing the level of acid formation promotes healing of gastric ulcers.

The full indication is: As an aid in the treatment of NSAID-induced gastric ulceration in dogs.

The most common side effects with very common frequency, i.e. >1 animal / 10 animals treated, are reduced food intake (transient and may be observed in the first week of treatment), weight loss and elevated cholesterol (total).

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 Omeprazole TriviumVet 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union