5 June 2015
EMA/CVMP/292500/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

UpCard

International non-proprietary name (INN): Torasemide

On 4 June 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the veterinary medicinal product UpCard tablets, intended for the treatment of clinical signs, including oedema and effusion, related to congestive heart failure in dogs. The applicant for this veterinary medicinal product is Vétoquinol SA. They may request a re-examination of the CVMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of UpCard is torasemide (anhydrous), a diuretic (ATCvet code QC03CA04). Torasemide works by increasing the amount of urine excreted from the kidneys to clear excess fluid from the body resulting from heart failure.

The benefit of UpCard is its efficacy in the treatment of clinical signs, including oedema and effusion, related to congestive heart failure in dogs. The most common side effects are increases in renal blood parameters, renal insufficiency, haemoconcentration, polyuria and/or polydipsia.

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 UpCard 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact