21 May 2012
EMA/CVMP/273464/2012
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Cardalis

Benazepril hydrochloride/spironolactone

On 16 May 2012, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[2] recommending the granting of a marketing authorisation for the veterinary medicinal product Cardalis 2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg tablets. Cardalis tablets are intended for the treatment of congestive heart failure in dogs caused by chronic degenerative valvular disease (with diuretic support, as appropriate).

The applicant for this veterinary medicinal product is Ceva Santé Animale.

The active substances in Cardalis tablets are benazepril hydrochloride which is an angiotensin converting enzyme (ACE) inhibitor, and spironolactone which is an aldosterone antagonist. The ATCvet code for the combination is QC09BA07.

Spironolactone inhibits aldosterone-induced sodium retention in the kidney, leading to an increase in sodium, and subsequently water, excretion, thereby decreasing cardiac preload. Laboratory studies demonstrate that in the cardiovascular system spironolactone inhibits aldosterone induced fibrosis and improves endothelial function.

Benazepril inhibits ACE which leads to reduced conversion of inactive angiotensin I into angiotensin II and therefore reduction in the effects mediated by angiotensin II, including vasoconstriction of both arteries and veins, retention of sodium and water by the kidney and remodelling effects (including pathological cardiac hypertrophy and degenerative renal changes).

The benefits of Cardalis are that dogs treated with benazepril hydrochloride and spironolactone demonstrated an increased survival compared to dogs treated with benazepril alone. As it is a fixed combination product, it is only suitable for dogs which require both active substances at this fixed dose ratio.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[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 most common side effect is that a reversible prostatic atrophy is often observed in entire male dogs; this is attributable to the spironolactone component of the fixed combination.

The approved indication is: “For the treatment of congestive heart failure caused by chronic degenerative valvular disease in dogs (with diuretic support as appropriate).”

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 to risk balance for Cardalis and therefore recommends the granting of the marketing authorisation.