



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

10 July 2015  
EMA/CVMP/274376/2015  
Committee for Medicinal Products for Veterinary Use

## Summary of opinion<sup>1</sup> (initial authorisation)

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### FORTEKOR PLUS

International non-proprietary names (INN): pimobendan / benazepril

On 9 July 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion<sup>2</sup>, recommending the granting of a marketing authorisation for the veterinary medicinal product FORTEKOR PLUS 1.25 mg/2.5 mg and 5 mg/10 mg tablets, intended for the treatment of congestive heart failure due to atrioventricular valve insufficiency or dilated cardiomyopathy in dogs. The applicant for this veterinary medicinal product is Elanco Europe Ltd.

FORTEKOR PLUS is a fixed combination product containing benazepril hydrochloride and pimobendan. (ATCvet QC09BX90) as active substance.

Benazepril hydrochloride is an angiotensin converting enzyme (ACE) inhibitor. 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).

Pimobendan is a non-sympathomimetic, non-glycoside inotropic substance with potent vasodilating properties. It increases the calcium sensitivity of cardiac myofilaments and inhibits phosphodiesterase (type III). It also exhibits a vasodilatory action through the inhibition of phosphodiesterase type III activity.

The benefit of FORTEKOR PLUS is its efficacy in the treatment of congestive heart failure due to atrioventricular valve insufficiency or dilated cardiomyopathy in dogs. FORTEKOR PLUS is a fixed dose combination and should only be used in patients whose clinical signs are successfully controlled by administration of the same doses of the individual components (pimobendan and benazepril hydrochloride) given concurrently.

The most common side effects are of a non-serious nature and would include increased heart rate, occasional vomiting, incoordination or signs of fatigue.

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<sup>1</sup> Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.

<sup>2</sup> 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.



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 FORTEKOR PLUS and therefore recommends the granting of the marketing authorisation.