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Veterinary Medicines

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Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 6(12)[1] referral for Vasotop P tablet for dogs

International non-proprietary name (INN): ramipril

Background information

Vasotop P 0.625 mg, Vasotop P 1.25 mg and Vasotop P 2.5 mg tablets are veterinary medicinal products that contain the active ingredient ramipril at concentrations of 0.625 mg, 1.25 mg and 2.5 mg respectively. Ramipril is an angiotensin-converting enzyme (ACE) inhibitor. The products are currently authorised for use in dogs for the treatment of congestive heart failure (NYHA classification grade II, III and IV) due to chronic degenerative valvular heart disease or cardiomyopathy, with or without adjunct diuretic (furosemide) or cardiac glycoside (digoxin/methyldigoxin) therapy.

The marketing authorisation holder (Intervet International B.V.) submitted applications for a type II variation subject to mutual recognition procedures for Vasotop P 0.625 mg, Vasotop P 1.25 mg and Vasotop P 2.5 mg tablets for dogs in order to include a new indication for cats as follows: *For the reduction of elevated systolic blood pressure (between 160 and 230 mm Hg) and the control of associated clinical signs*. The application was submitted in the framework of Article 6 of Commission Regulation (EC) No 1084/2003, where the reference Member State was Germany and the concerned Member States were Austria, Belgium, Denmark, Greece, Spain, Finland, Ireland, Italy, Luxemburg, the Netherlands, Norway, Portugal and Sweden. The mutual recognition procedures (DE/V/0103/001/II/007, DE/V/0103/002/II/007 and DE/V/0103/004/II/007) started on 3 December 2008.

On 2 July 2009 Belgium referred the matter to the Agency under Article 39 of Directive 2001/82/EC as amended by reference to Article 6(12) of Regulation (EC) No 1084/2003 due to concerns whether the marketing authorisation should be varied by adding cats as a new target species by considering if a placebo group is deemed necessary in a clinical field trial to assess the efficacy of ramipril in cats to reduce systolic blood pressure.

[1] Article 6(12) of Regulation (EC) No 1084/2003.

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The referral procedure started on 14 July 2009. The rapporteur and co-rapporteur appointed were Dr. R. Breathnach and Dr. M. Holzhauser-Alberti respectively. Written explanations were provided by the marketing authorisation holder on 17 August 2009. Oral explanations were given on 11 November 2009.

Further to rapporteurs' assessment of the currently available data, the CVMP adopted on 8 December 2009 an opinion recommending that the variation application for the veterinary medicinal products Vasotop P 0.625 mg tablet for dogs, Vasotop P 1.25 mg tablet for dogs and Vasotop P 2.5 mg tablet for dogs and associated names does not satisfy the criteria for approval in respect of efficacy.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II.

The final opinion was converted into a Decision by the European Commission on 27 April 2010.