16 January 2015
EMA/CVMP/739062/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Lodipressin

International non-proprietary name (INN): amlodipine

On 15 January 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion[2], recommending the refusal of the granting of a marketing authorisation for the veterinary medicinal product Lodipressin 1 mg tablets for cats.

The applicant for this veterinary medicinal product is Le Vet Beheer B.V., registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

The active substance in Lodipressin tablets is amlodipine (as amlodipine besilate), a calcium ion influx inhibitor of the dihydropyridine group which inhibits calcium influx in smooth muscle cells in the heart and blood vessels. The product was intended for the treatment of systemic arterial hypertension in cats. The ATCvet code is QC08CA01.

The grounds for the negative opinion relate to efficacy, user safety and quality.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that the benefit-risk balance for Lodipressin was not demonstrated to be favourable and therefore cannot recommend the granting of a marketing authorisation.

[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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