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Questions and answers

Refusal of the marketing authorisation for Lodipressin (amlodipine besilate)

Outcome of re-examination

On 15 January 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Lodipressin, intended for the treatment of systemic arterial hypertension in cats. The company that applied for authorisation is Le Vet Beheer B.V.

The applicant requested a re-examination of the opinion. After considering the grounds for this request, the CVMP re-examined the initial opinion, and confirmed the refusal of the marketing authorisation on 7 May 2015.

What is Lodipressin?

Lodipressin is a veterinary medicine that contains the active substance amlodipine besilate. It was to be available as tablets.

What was Lodipressin expected to be used for?

Lodipressin was expected to be used to treat cats with systemic arterial hypertension (high blood pressure).

How is Lodipressin expected to work?

Amlodipine is a calcium channel blocker. This means that it blocks channels on the surface of cells through which calcium normally enters the cell. When calcium enters the cells in the blood vessel walls this causes contraction. By reducing the entry of calcium into these cells, amlodipine prevents the blood vessel from contracting, thus lowering the blood pressure.

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What did the company present to support its application?

As part of its application the company presented the results of a field study involving cats with blood pressure of 160 mmHg or above. The study had two parts, an initial part with 19 cats, 11 of which were treated with Lodipressin and 8 of which received placebo (a dummy treatment) for two weeks. In the second part, 23 cats received Lodipressin for 16 weeks with no placebo group.

What were the CVMP's main concerns that led to the refusal?

At the time of the initial evaluation, the CVMP considered that there were deficiencies in the way the field study had been designed and conducted and the results had been presented. This meant that whilst there is some evidence that Lodipressin is effective in lowering blood pressure, no firm conclusions could be drawn on its effectiveness for treatment of high blood pressure in cats. In addition, there were concerns that the safety of the medicine had not been fully demonstrated and one unresolved quality issue.

During the re-examination, the CVMP considered advice from an expert group in feline medicine. The expert group advised that although the field study showed some evidence of a reduction in blood pressure, the many shortcomings in the study did not allow to conclude that the benefits of Lodipressin in the treatment of high blood pressure in cats outweigh the risks. The CVMP therefore maintained its recommendation that the marketing authorisation be refused.