14 December 2012
EMA/CVMP/734633/2012
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Pexion

Imepitoin

On 13 December 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 Pexion 100 mg and 400 mg tablets, intended for the reduction of the frequency of generalised seizures due to idiopathic epilepsy in dogs. The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

The active substance of Pexion is imepitoin. Imepitoin is a centrally acting antiepileptic substance (ATC vet code QN03AX90) which inhibits seizures via potentiation the $GABA_A$ receptor-mediated inhibitory effects on the neurons. In addition, imepitoin has a weak calcium channel blocking effect.

The benefits of Pexion are its potential safety benefit in comparison with the standard treatment and the increase in range of available treatment possibilities for idiopathic epilepsy. The most common side effects are polyphagia, hyperactivity, polyuria, polydypsia, somnolence, hypersalivation, emesis, ataxia, apathy, diarrhoea, prolapsed nictitating membrane, decreased sight and sensitivity to sound.

The approved indication is: “For the reduction of the frequency of generalised seizures due to idiopathic epilepsy in dogs for use after careful evaluation of alternative treatment options.”

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 Pexion and therefore recommends the granting of the 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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