EPAR summary for the public

**Pexion**

Imepitoin

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal’s medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

**What is Pexion?**

Pexion is a veterinary medicine that contains imepitoin. It is available as tablets (100 mg and 400 mg).

**What is Pexion used for?**

Pexion is used in dogs to reduce the frequency of generalised seizures (fits affecting most or all of the brain) due to epilepsy of unknown causes (idiopathic). It should be used after careful evaluation of alternative treatment options.

Treatment with Pexion should be started at a dose of 10 mg per kg bodyweight twice a day. If seizures are not adequately controlled after one week, the veterinary surgeon may increase the dose in weekly increments to a maximum of 30 mg per kg bodyweight twice a day.

**How does Pexion work?**

The active substance in Pexion, imepitoin, is an anti-epileptic medicine. Epilepsy is caused by excessive electrical activity in the brain. Imepitoin partially activates the receptors for the neurotransmitter GABA in the brain. Neurotransmitters such as GABA are chemicals that allow nerve cells to communicate with each other. In the brain GABA is involved in reducing the electrical activity. By activating its receptors, imepitoin increases GABA’s effects and helps to prevent seizures. Imepitoin also has a weak blocking
Effect on calcium channels. These are pores which let calcium move into the nerve cells allowing electrical impulses to be transmitted between nerve cells. This may also help in controlling seizures.

**How has Pexion been studied?**

Pexion has been compared to phenobarbital (another anti-epileptic medicine) in one main study, a field study involving 226 dogs of approximately 70 breeds and aged 0.8 to 15 years. The study, which lasted for 20 weeks, consisted of an initial phase of 8 weeks to establish the dose and an evaluation phase of 12 weeks. The main measure of effectiveness was the number of seizures in a month. The study also looked at the proportion of dogs that had no seizures.

**What benefit has Pexion shown during the studies?**

Pexion reduced the average number of generalised seizures from 2.3 to 1.1 per month after 20 weeks of treatment compared with a reduction of 2.4 seizures to 1.1 per month with phenobarbital. During the evaluation phase of 12 weeks, 47% (30 out of 64) of Pexion treated dogs were free from generalised seizures, whilst 58% (51 out of 88) of phenobarbital treated dogs had no seizures.

Even though the proportion of seizure free dogs was lower with Pexion than with phenobarbital, some dogs were well controlled with Pexion. As side effects were less frequent than with phenobarbital, Pexion is a suitable treatment option for some dogs, considering in particular its safety profile.

**What is the risk associated with Pexion?**

Mild and generally short-lived side effects with Pexion were polyphagia (excessive eating), hyperactivity, polyuria (increased volume of urine), polydipsia (excessive water intake), somnolence (sleepiness), hypersalivation, emesis (vomiting), ataxia (inability to coordinate muscle movements), apathy (lack of interest in surroundings), diarrhea, prolapsed nictitating membrane (protrusion across the eye of the ‘third eyelid’), decreased sight and sensitivity to sound. For a full list of all side-effects reported with Pexion, see the package leaflet.

Pexion must not be used in dogs that are hypersensitive (allergic) to the active ingredient or to any of the ingredients. It must also not be used in dogs with severely impaired liver, kidney or heart function.

The effectiveness of Pexion to treat dogs with status epilepticus and cluster seizures has not been studied. Therefore, Pexion should not be used as a primary treatment for dogs with cluster seizures (group of seizures occurring close together) and status epilepticus (continual seizures).

**What are the precautions for the person who gives the medicine or comes into contact with the animal?**

In case of accidental ingestion, especially by a child, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

To prevent accidental ingestion, the bottle cap should be replaced immediately after withdrawing the required number of tablets for one dose.

**Why has Pexion been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Pexion exceed the risks for the approved indications and recommended that Pexion be given a marketing authorisation. The benefit/risk balance may be found in the scientific discussion module of this EPAR.
Other information about Pexion:

The European Commission granted a marketing authorisation valid throughout the European Union, for Pexion on 25 February 2013. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 25 February 2013.