EMA/807398/2012
EMEA/V/C/002543

EPAR summary for the public

Pexion

imepitoin

This is a summary of the European public assessment report (EPAR) for Pexion. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Pexion.

For practical information about using Pexion, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Pexion and what is it used for?

Pexion is a veterinary medicine 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. Pexion contains the active substance imepitoin.

How is Pexion used?

Pexion is available as tablets and can only be obtained with a prescription. The dose is calculated according to the dog's weight: 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 by 50 – 100%, 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, a substance that reduces electrical activity in the brain. Neurotransmitters such as GABA are chemicals that allow nerve cells to communicate with each other. 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.

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What benefits of Pexion have been shown in studies?

In an EU field study involving 226 dogs Pexion at a dose of 10 - 30 mg/kg twice daily reduced the average number of generalised seizures from 2.3 to 1.1 per month after 20 weeks of treatment. This compared with a reduction of 2.4 seizures to 1.1 per month with phenobarbital (another anti-epileptic medicine). 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.

In a second US field study involving 151 dogs, Pexion treatment for 12 weeks at a fixed dose of 30 mg/kg twice daily resulted in 21% of dogs (21 out of 99) being free of generalised seizures compared to 8% of dogs (4 out of 52) given a dummy treatment. 25% of dogs did not respond to Pexion treatment and had the same or an increased number of seizures.

What are the risks associated with Pexion?

Mild and generally short-lived side effects with Pexion were polyphagia (excessive eating), anorexia (loss of appetite), 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), diarrhoea, disorientation, prolapsed nictitating membrane (protrusion across the eye of the 'third eyelid'), decreased sight and sensitivity to sound.

Pexion must 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).

For a full list of all side-effects and restrictions with Pexion, see the package leaflet.

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 is Pexion approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Pexion's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Pexion:

The European Commission granted a marketing authorisation valid throughout the EU for Pexion on 25 February 2013.

The full EPAR for Pexion can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Pexion, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in June 2017.