



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Pexion (*imepitoin*)

An overview of Pexion and why it is authorised in the EU

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;
- reduce anxiety and fear associated with noise phobia.

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.

For epilepsy, 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% at a time, to a maximum of 30 mg per kg bodyweight twice a day.

For noise phobia, treatment with Pexion is given at a dose of 30 mg per kg bodyweight twice a day, starting 2 days before an expected noise event and continuing through it.

How does Pexion work?

The active substance in Pexion, imepitoin, is an anti-epileptic and anti-anxiety 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. Imepitoin's effect on GABA receptors also reduces fear and anxiety.



What benefits of Pexion have been shown in studies?

In an EU field study looking at effects on epilepsy, Pexion at a dose of 10 to 30 mg/kg bodyweight 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 looking at effects on epilepsy and involving 151 dogs, Pexion treatment for 12 weeks at a fixed dose of 30 mg/kg bodyweight 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.

In an EU field study looking at effects on noise phobia, the effectiveness of 3 days' treatment with Pexion, at a dose of 30 mg/kg bodyweight twice daily, was investigated during New Year's Eve fireworks in dogs diagnosed with noise phobia. Out of 104 Pexion-treated dogs, 64% showed a good or excellent effect compared to 25% of 122 dogs receiving dummy treatment (placebo) as reported by owners. Pexion-treated dogs also had reduced anxiety scores compared to the placebo group.

What are the risks associated with Pexion?

For epilepsy, the most common side effects with Pexion (which may affect more than 1 in 10 dogs) are ataxia (inability to coordinate muscle movements), vomiting, polyphagia (excessive eating), and somnolence (sleepiness). These side effects are mild and generally short-lived.

For noise phobia, the most common side effects with Pexion (which may affect more than 1 in 10 dogs) are short-lived ataxia, increased appetite, and lethargy (lack of energy).

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 the full list of side effects and restrictions of Pexion, see the package leaflet.

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

Ingestion of this medicine may cause dizziness, lethargy and nausea. 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 authorised in the EU?

The European Medicine Agency decided that Pexion's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Pexion

Pexion received a marketing authorisation valid throughout the EU on 25 February 2013.

Further information on Pexion can be found on the Agency's website: ema.europa.eu/Find_medicine/Veterinary_medicines/European_public_assessment_reports.

This overview was last updated in May 2018.