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Sevohale[1] (*sevoflurane*)

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

What is Sevohale and what is it used for?

Sevohale is a general anaesthetic for dogs and cats. Sevohale is used to bring about and maintain general anaesthesia (loss of consciousness). It contains the active substance sevoflurane, a chemical which is a liquid at room temperature, but when heated becomes a gas (vaporises).

Sevohale is a 'generic medicine'. This means that Sevohale contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called SevoFlo.

For more information, see the package leaflet.

How is Sevohale used?

Sevohale is given using specialised anaesthetic equipment, usually in a carefully controlled mixture including oxygen. The dog or cat breathes in this gas mixture, which causes it to become unconscious. The medicine can only be obtained with a prescription. For more information about using Sevohale, see the package leaflet or contact your veterinarian or pharmacist.

How does Sevohale work?

When a dog or cat is given a mixture of oxygen and sevoflurane to breathe, the sevoflurane is inhaled into its lungs and is carried by the blood into the brain. Sevoflurane mimics the action of GABA, a substance that naturally reduces brain activity, and blocks the action of glutamate, which stimulates the action of the brain. Together, these combined actions result in loss of consciousness.

How has Sevohale been studied?

No additional studies were needed as Sevohale is a generic medicine that is given by inhalation and contains the same active substance as the reference medicine, SevoFlo.

What are the benefits and risks of Sevohale?

Because Sevohale is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

[1] Previously known as Sevocalm

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

Safety information has been included in the summary of product characteristics and the package leaflet for Sevohale, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers. The precautions are the same as for the reference medicine since Sevohale is a generic medicine.

Why is Sevohale authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Sevohale has been shown to be comparable to SevoFlo. Therefore, the Agency's view was that, as for SevoFlo, the benefits outweigh the identified risks and it can be authorised for use in the EU.

Other information about Sevohale

Sevocalm received a marketing authorisation valid throughout the EU on 21/06/2016. The name of the medicine was changed to Sevohale on 29 July 2016.

Further information on Sevohale can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports.

Information on the reference medicine can also be found on the Agency's website.

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