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EPAR summary for the public

Sedadex

dexmedetomidine

This is a summary of the European public assessment report (EPAR) for Sedadex. 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 Sedadex.

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

What is Sedadex and what is it used for?

Sedadex is a medicine used to sedate (calm down) and relieve pain in dogs and cats:

- when carrying out mildly to moderately painful procedures and examinations that require the animal to be restrained or sedated and made less sensitive to pain (analgesia) but are non-invasive (do not involve breaking the skin or a body cavity).
- as premedication (treatment given before inducing general anaesthesia).
- Sedadex can also be used in dogs to provide pain relief and deep sedation when carrying out medical procedures and minor surgery where it is used in combination with butorphanol (a sedative and analgesic).

Sedadex contains the active substance dexmedetomidine and is a 'generic medicine'. This means that Sedadex is similar to a 'reference medicine' already authorised in the EU called Dexdomitor.

For further information, see the package leaflet.

How is Sedadex used?

Sedadex is available as a solution for injection and can only be obtained with a prescription.

In dogs, Sedadex is given by injection into a vein or a muscle. In cats, it is given by intramuscular injection. The dose in each species depends on the body surface area in dogs (calculated using bodyweight) and bodyweight in cats, and on the use, type of injection and any other medicines that are being used. The duration and depth of sedation and analgesia relate to the dose that is used.

How does Sedadex work?

Dexmedetomidine is an alpha2-adrenoceptor agonist. It works by preventing the release of the neurotransmitter noradrenaline from nerve cells in the body. A neurotransmitter is a substance that nerve cells use to communicate with neighbouring cells. Since noradrenaline is involved in maintaining alertness and arousal, reducing its release decreases the level of consciousness, including the sensation of pain. Dexmedetomidine is closely related to another substance used to sedate animals, medetomidine, that has been used in veterinary medicine for many years.

How has Sedadex been studied?

The company provided information on the quality and manufacture of Sedadex. No additional studies were needed as Sedadex is a generic medicine that is given by injection, is similar in composition to, and contains the same active substance as, the reference medicine, Dexdomitor.

What are the benefits and risks of Sedadex?

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

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 Sedadex, 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 Sedadex is a generic medicine.

Why is Sedadex approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that, in accordance with EU requirements, Sedadex has been shown to have comparable quality to Dexdomitor. Therefore, the CVMP's view was that, as for Dexdomitor, the benefits outweigh the identified risks. The Committee recommended that Sedadex be approved for use in the EU.

Other information about Sedadex?

The European Commission granted a marketing authorisation valid throughout the EU for Sedadex on 12 August 2016.

The full EPAR for Sedadex 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 Sedadex, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in June 2016.