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EPAR summary for the public

Dexdomitor

dexmedetomidine

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 Dexdomitor?

Dexdomitor contains the active substance dexmedetomidine, which belongs to a class of medicines having a psycholeptic (sedative) action. It is a solution for injection (0.1 mg/ml and 0.5 mg/ml).

What is Dexdomitor used for?

Dexdomitor is used to sedate (calm down) dogs and cats in the following situations:

- 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). It is used in non-invasive procedures which do not involve breaking the skin or a body cavity.
- Before inducing general anaesthesia. When used in cats, ketamine should be used as the anaesthetic agent.
- For deep sedation and analgesia in dogs in combination with butorphanol (a sedative and analgesic) for procedures including minor surgery.

The dose is chosen according to the species being treated, the use, whether it is given by intravenous (into a vein) or intramuscular (into a muscle) injection and any other medicines that are also being used. The dose depends on the body surface area in dogs (calculated using bodyweight) and

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bodyweight in cats. In dogs, Dexdomitor is given by intravenous or intramuscular injection. In cats, it is given by intramuscular injection. The duration and depth of sedation and analgesia depend on the dose that is used.

How does Dexdomitor work?

Dexmedetomidine is an alpha2-adrenoceptor agonist. It works by preventing the release of the neurotransmitter noradrenaline from nerve cells in the body. Neurotransmitters are chemicals that allow nerve cells to communicate with each other. 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 Dexdomitor been studied?

Dexdomitor was investigated in studies involving dogs and cats in which its effectiveness was compared with that of medetomidine. The studies included dogs and cats of various ages and breeds, which were undergoing procedures requiring sedation or analgesia. In dogs, both intravenous and intramuscular injections of Dexdomitor were studied.

Dexdomitor was also compared with medetomidne for premedication (sedation prior to anaesthesia) in cats about to undergo general anaesthesia with ketamine and for deep sedation of dogs in combination with butorphanol. Finally, it was studied as a premedication in dogs and cats prior to induction of general anaesthesia.

What benefit has Dexdomitor shown during the studies?

The studies showed that Dexdomitor had an equivalent level of effectiveness as medetomidine in inducing sedation and analgesia in dogs and cats. As for medetomidine, ‘good’ or ‘excellent’ analgesia was reached in about 40 to 50 % of the animals, supporting its used in non-invasive mildly to moderately painful procedures.

Dexdomitor was at least as effective as medetomidine in inducing general anaesthesia in cats in combination with ketamine. Dexdomitor also showed adequate effectiveness for deep sedation of dogs in combination with butorphanol, and for premedication in dogs and cats before induction of general anaesthesia, reducing the amount of anaesthetic that the dogs and cats require.

What is the risk associated with Dexdomitor?

Dexdomitor causes a decrease in heart rate and body temperature. In addition, the blood pressure will increase before returning to normal or below normal. In some dogs and cats, there may be a decrease in breathing rate and the mucous membranes may appear pale or with a blue tinge. Vomiting may occur five to 10 minutes after injection or at the time of recovery. Muscle tremors (shaking) and corneal opacities (cloudy spots in the cornea, the clear part of the eye in front of the pupil) may occur during sedation. Other side effects can occur when Dexdomitor is used with other medicines. For a full list of all side effects reported with Dexdomitor, see the package leaflet.

It should not be used in animals that have problems with their heart or blood vessels, with severe systemic (whole body) disease, that are moribund (close to death) or that are known to be hypersensitive (allergic) to dexmedetomidine or any of the other ingredients.

The safety of the use of Dexdomitor has not been studied in puppies below 16 weeks of age or in kittens below 12 weeks of age.

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

If Dexdomitor is accidentally self-injected or taken by mouth, medical advice should be sought immediately and the package leaflet or the label shown to the doctor. However, the person should not drive due to the risk of sedation and changes in blood pressure. Contact with the skin, eyes of mucous (moist body surfaces) should be avoided. If contact does occur, rinsing with large amounts of water is advised. The use of waterproof gloves is advisable. Pregnant women should take special care to avoid self-injection. People who are known to be hypersensitive to dexmedetomidine or any of the other ingredients should give the medicine with caution.

Why has Dexdomitor been approved?

The CVMP concluded that the benefits of Dexdomitor exceed the risks and recommended that it be given a marketing authorisation. The benefit/risk balance may be found in the scientific discussion module of this EPAR.

Other information about Dexdomitor:

The European Commission granted a marketing authorisation valid throughout the European Union, for Dexdomitor on 30 August 2002. The marketing authorisation was renewed on 2 August 2007. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 30/08/2012.