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**EPAR summary for the public**

# Cepedex

dexmedetomidine

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

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

## What is Cepedex and what is it used for?

Cepedex is a medicine 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). Cepedex is used in non-invasive procedures which do not involve breaking the skin or a body cavity.
- as premedication before inducing general anaesthesia.

Cepedex 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).

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

For further information, see the package leaflet.

## How is Cepedex used?

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

In dogs, Cepedex is given by injection into a vein or a muscle. In cats, it is given by injection into a muscle. For dogs the dose depends on their body surface area (calculated using bodyweight) and in cats it is based on bodyweight. It also depends on the use and the way it is given. The duration and depth of

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

sedation and analgesia depend on the dose that is used.

## How does Cepedex work?

Cepedex is an alpha2-adrenoceptor agonist. It works by attaching to receptors known as alpha2-adrenergic receptors and 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 Cepedex been studied?

The company provided information on the quality and manufacture of Cepedex. No additional studies were needed as Cepedex 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 Cepedex?

Because Cepedex 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 Cepedex, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers when giving Cepedex. Because Cepedex is a generic medicine and is bioequivalent to the reference medicine the precautions are the same as for the reference medicine.

## Why is Cepedex approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that, in accordance with EU requirements, Cepedex 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 Cepedex be approved for use in the EU.

## Other information about Cepedex?

The European Commission granted a marketing authorisation valid throughout the EU for Cepedex on 13 December 2016.

The full EPAR for Cepedex 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 Cepedex, 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 October 2016.