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EPAR summary for the public

Cerenia

Maropitant

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 Cerenia?

Cerenia is a medicine that contains the active substance maropitant. It is available as tablets (16, 24, 60 and 160 mg) for dogs, and as a solution for injection (10 mg/ml) under the skin or into a vein for dogs and cats.

What is Cerenia used for?

Cerenia is used to treat vomiting in dogs and cats (solution for injection) or to prevent vomiting in dogs (tablets), in combination with other supportive measures. In dogs the tablets can be used to prevent vomiting due to motion sickness. In cats the solution for injection is used to prevent vomiting and to reduce nausea, but is not suitable for motion (travel) sickness.

Cerenia solution for injection is used in dogs both to prevent nausea and vomiting before and after an operation and to improve recovery from general anaesthesia after use of morphine. Cerenia is used to prevent (tablets and solution for injection) and treat (solution for injecton) nausea caused by chemotherapy in dogs.

Cerenia solution for injection is given to dogs and cats once daily under the skin or into a vein (1 mg per kg bodyweight) for up to five days. Cerenia tablets are given to dogs at a dose of 2 mg maropitant per kg bodyweight once daily to prevent or treat vomiting for up to 14 days. Cerenia tablets are given

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to dogs at a dose of 8 mg maropitant per kg bodyweight once daily to prevent vomiting due to motion sickness for a maximum of two consecutive days.

How does Cerenia work?

Cerenia blocks neurokinin-1 (NK1) receptors, which are found on the surface of certain cells in the part of the brain that controls nausea and vomitingand are activated by the attachment of a chemical in the body called 'substance P'. By preventing the attachment of substance P to the receptors, Cerenia prevents them from being activated and so reduces nausea and vomiting.

How has Cerenia been studied?

A large number of studies with Cerenia were carried out either in laboratory dogs and cats or in animal patients at veterinary practices in several European countries and in the USA. Bioequivalence studies were conducted in both dogs and cats to compare giving the injection under the skin with injection into a vein.

Dogs:
For the prevention of vomiting, Cerenia was studied in dogs which received either Cerenia or a placebo (a dummy tablet or injection) before another substance known to trigger vomiting (such as certain cancer medicines) was given to them. For the treatment of vomiting, the effect of Cerenia (or a placebo) was examined in sick dogs that were vomiting for various reasons, for example because of a gastrointestinal infection. Most of these dogs also received additional treatment. Dogs were treated with either 1 mg/kg (injection given under the skin) or 2 mg/kg (tablet) once daily up to five days.

In order to study the effect of Cerenia in motion sickness, dogs prone to vomiting when travelling were taken on car journeys lasting several hours for up to two consecutive days. The animals received either Cerenia tablets at a dose of 8 mg/kg bodyweight or a placebo for up to two consecutive days.

A further study involving dogs looked at the prevention of nausea and vomiting before and after surgery. Dogs received either Cerenia soluton for injection or placebo 45 minutes before the administration of morphine for sedation and pain relief prior to anaesthesia . The measures of effectiveness were evidence of retching, vomiting, intensity of nausea and improvements in the speed of recovery by for example measuring time to sit up and stand.

Cats:
For the prevention of vomiting, Cerenia was studied in cats which received either Cerenia or placebo before another substance known to trigger vomiting was given to them. For the treatment of vomiting, the effect of Cerenia compared with placebo was examined in sick cats that were vomiting for various reasons. Cats were treated with 1 mg/kg (injection given under the skin) once daily up to five days.

What benefit has Cerenia shown during the studies?

The bioequivalence studies showed that giving the injection under the skin produced the same levels of maropitant in the body as giving the injection into a vein.

The results of the studies showed that Cerenia was more effective than placebo: less vomiting was seen in dogs and cats that received the medicine than in animals that received placebo, both in the treatment or in the prevention of vomiting. For dogs, the treatment of vomiting should be started with the injection, since vomiting animals might throw the intact tablet up again. For follow-up treatment,

the animal owner can administer the tablets to the dog. In cats, treatment of vomiting is with the injection only. Also, the treatment of vomiting should only be together with other supportive measures or other veterinary therapy while addressing the underlying causes of the vomiting.

In the study looking at the effect of Cerenia before and after surgery, Cerenia was effective at preventing vomiting asociated with the use of morphine. Only one out of 16 dogs given Cerenia vomited after receiving morphine, whilst 14 out of 15 dogs given placebo vomited, and in this group, nine of the dogs that vomited did so more than once.

What is the risk associated with Cerenia?

Cerenia was generally well tolerated.

A common side effect of the tablets when used at a high dose of 8 mg/kg in dogs (for motion sickness) was vomiting before the car journey started. Since this was mainly observed in dogs with an empty stomach, it is recommended to feed a light meal or snack a while before the tablets are given. Other reported side effects were decreased activity levels and tiredness.

A very common side effect in cats was evidence of pain from injection under the skin and this may be reduced by injection of the product at refrigerated temperature.

The active substance in Cerenia, maropitant, is broken down in the liver and therefore it is recommended to be used with caution in animals with liver disease. Since maropitant could affect heart activity, Cerenia should be used with caution in animals with certain heart conditions.

Since Cerenia has not been studied in very young dogs or cats, or in pregnant or lactating bitches or queens, use of Cerenia in these animals should be discussed with your veterinarian.

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

Handling Cerenia does not represent a particular risk for people.However, maropitant can produce short lived eye irritation and in the case of accidental eye exposure, the eyes should be flushed with plenty of water and medical attention sought. In case of accidental ingestion or self-injection medical advice should be sought immediately and the package leaflet or the label shown to the physician.

As injection under the skin causes pain in cats, the animal will need to be restrained when treated.

Why has Cerenia been approved?

The CVMP concluded that the benefits of Cerenia exceed its risks and recommended that Cerenia be given a marketing authorisation. The benefit-risk balance can be found in the scientific discussion module of this EPAR.

Other information about Cerenia:

The European Commission granted a marketing authorisation valid throughout the European Union, for Cerenia on 29/09/2006. Information on the prescription status of this product can be found on the label/outer package.

This summary was last updated in April 2015.