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EPAR summary for the public

CONVENIA

cefovecin

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 Convenia?

Convenia contains ceftiofur, an antibiotic which is given by injection (under the skin). It is used for dogs and cats.

There are two vials in each pack of Convenia, one vial containing a powder, and one vial containing the diluent. The powder is dissolved in the diluent before use to make up a solution for injection.

What is Convenia used for?

Convenia is used to treat infections caused by certain specific bacteria (see the SPC for further details). It is generally given as a single injection, and the effect of the injection lasts for up to 14 days. Depending on the infection concerned, the injection can be repeated if necessary (up to three times).

Convenia is used in dogs to treat skin and soft tissue infections; these are infections on the skin and in the layers just below the skin, such as wounds, abscesses and pyoderma (a skin infection with a rash and pustules). It is also used in dogs to treat urinary tract infections caused by certain specific bacteria.



Convenia is used in cats to treat skin and soft tissue infections, such as wounds and abscesses. It is also used in cats to treat urinary tract infections caused by certain specific bacteria.

How does Convenia work?

The active substance in Convenia is cefovecin which belongs to a class of antibiotics called third generation cephalosporins. All these cephalosporin antibiotics, including cefovecin, kill bacteria by disrupting the building of the bacterial cell walls, so the bacteria die and the infection is cured. Like other antibiotics, cefovecin is not effective against all types of bacteria.

Cefovecin differs from other similar cephalosporin antibiotics as it stays in the dog's or cat's body for a very long time after it has been injected. One injection lasts for up to 14 days.

How has Convenia been studied?

Data from laboratory studies with different bacteria showed that cefovecin was effective against the bacteria specified in the product information (SPC and package leaflet).

Convenia has been studied in dogs with skin and soft tissue infections (where it was compared to another antibiotic containing amoxicillin and clavulanic acid) and in dogs with urinary tract infections (where it was compared to another cephalosporin antibiotic, cefalexin).

Convenia has also been studied in cats with skin and soft tissue infections (where it was compared to another antibiotic containing amoxicillin and clavulanic acid), and in a small study in cats with urinary tract infections, where it was compared with cefalexin.

The studies measured the rate at which the infections were cured.

What benefit has Convenia shown during the studies?

In all studies, Convenia was as effective in curing the infection as the comparator antibiotic. Convenia has the benefit of a long duration of activity.

What is the risk associated with Convenia?

No side-effects have been reported with Convenia to date. However, it should not be used in dogs or cats which have shown an allergy to any cephalosporin or penicillin-type antibiotics.

Convenia should also not be used in dogs or cats of less than 8 weeks old, or in dogs or cats with severe kidney problems (renal dysfunction).

It would be dangerous to use Convenia in other animals such as guinea pigs and rabbits (it is not licensed for use in these species).

As no studies have been made in breeding animals with Convenia and it has an exceptionally long duration in the body, Convenia should not be used in pregnant or lactating dogs or cats. Treated animals should not be used for breeding for 12 weeks after the last injection of Convenia.

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

Cephalosporin and penicillin antibiotics can cause allergies in humans, and sometimes these allergies can be very serious. Convenia should therefore not be handled by anyone who is

hypersensitive (allergic) to such antibiotics, or by anyone who has been advised not to work with them. Anyone allergic to penicillins or cephalosporins should also avoid contact with litter used by dogs or cats treated with Convenia.

Convenia should be handled with care and all the recommended precautions be taken to avoid exposure to the product. If any symptoms occur after accidental exposure to Convenia, for example a skin rash, then the advice of a doctor should be sought immediately. Swelling of the face, lips or eyes, or any difficulty breathing are more serious symptoms and require urgent medical attention.

Why has Convenia been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Convenia exceed the risks for the treatment of dogs and cats with certain specified skin, soft tissue and urinary tract infections and recommended that Convenia should be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Convenia:

The European Commission granted a marketing authorisation valid throughout the European Union, for Convenia on 19 June 2006. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in: 04-2013.