



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/573644/2008
EMA/V/C/000031

EPAR summary for the public

Dicural

Difloxacin

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 Dicural?

Dicural contains the active substance difloxacin, which is an antibiotic. It is available as an oral solution for chickens and turkeys (100 mg/ml), as tablets for dogs (15 mg, 50 mg, 100 mg and 150 mg), and as a solution for injection for cattle and dogs (50 mg/ml).

What is Dicural used for?

Dicural is used to treat infections caused by bacteria:

- in chickens and turkeys, Dicural is used to treat certain infections affecting the respiratory system (lungs and air sacs). Dicural is only used in young turkeys of up to 2 kg body weight. For both chickens and turkeys it is given in the drinking water for five days;
- in dogs, Dicural is used to treat acute (short-lived) infections of the bladder and to treat pyoderma (a skin infection with a rash and raised lumps). It is given as tablets by mouth once a day for at least five days until the infection has been cured. On the first day of treatment, it can be given by injection under the skin before switching to the tablets;



- in cattle, Dicural is used to treat infections affecting the lungs and breathing (shipping fever and calf pneumonia). It is only used in calves and young cattle. Dicural is given once a day for up to five days as an injection under the skin.

For full details, see the Summary of Product Characteristics (SPC, also part of the EPAR).

How does Dicural work?

The active substance in Dicural, difloxacin, belongs to a group of antibiotics called 'fluoroquinolones'. Difloxacin works by blocking an enzyme called 'DNA gyrase', which is important in allowing bacteria to make copies of their DNA. By blocking the production of DNA, difloxacin stops the bacteria that are causing an infection from growing and multiplying. The full list of bacteria against which Dicural is active can be found in the SPC.

How has Dicural been studied?

In chickens and turkeys, nine main trials have been carried out in birds with respiratory system infections. One of these trials compared Dicural-treated birds with untreated birds, and another compared Dicural with enrofloxacin (another veterinary fluoroquinolone).

In dogs, four main trials looked at the effects of Dicural in treating bladder infections. Two of these studies compared Dicural with enrofloxacin and one compared it with the combination of amoxicillin and clavulanic acid (used together as an antibiotic). A further three trials looked at its effects in treating pyoderma: two compared it with enrofloxacin and one compared it with amoxicillin and clavulanic acid.

In cattle, seven main studies were carried out. All seven studies compared Dicural with enrofloxacin in calves.

What benefit has Dicural shown during the studies?

In all species, Dicural was effective in reducing the number of infected animals or reducing the severity of infection. Dicural was as effective as or slightly more effective than the comparator antibiotics.

What is the risk associated with Dicural?

In chickens and turkeys, no side effects from Dicural are known. However, since no studies have been performed in lame birds, Dicural must not be used in birds with existing leg weakness or osteoporosis (brittle bones).

In dogs, side effects from Dicural are rare, but include loss of appetite, vomiting, diarrhoea and anal irritation. These tend to disappear within one or two days and do not require additional treatment. Injection of Dicural solution for injection under the skin may result in some itching, local swelling and slight pain. The itching tends to disappear within a few minutes and the swelling within a few days. As for other fluoroquinolones, difloxacin should not be used in dogs that are growing quickly because it can affect the cartilage of some joints. This includes small- and medium-sized breeds up to and including eight months of age, large breeds up to one year of age and giant breeds up to 18 months of age. Dicural must not be used in epileptic dogs.

In cattle, injection of Dicural solution for injection under the skin may result in some temporary swelling at the site of the injection.

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

People who are hypersensitive (allergic) to quinolones (a group of antibiotics that includes the fluoroquinolones) should avoid any contact with Dicural.

When handling Dicural oral solution for chickens and turkeys, use gloves and a face-protecting device to avoid irritation of the skin or eyes.

What is the time to allow before the animal can be slaughtered and the meat used for human consumption (withdrawal period)?

Dicural must not be used in birds producing eggs for human consumption or within four weeks before the onset of the laying period.

After the last administration of Dicural, chickens and turkeys should not be slaughtered for 24 hours and cattle should not be slaughtered for 46 days.

Why has Dicural been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Dicural are greater than the risks for the treatment and recommended that Dicural be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Dicural:

The European Commission granted a marketing authorisation valid throughout the European Union, for Dicural on 16 January 1998. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in January 2012.