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EPAR summary for the public

Naxcel

Ceftiofur

This document is a summary of the European Public Assessment report for Naxcel. 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 regarding the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Naxcel?

Naxcel is an antibiotic suspension that contains ceftiofur (as crystalline free acid) as the active substance. It is available as a suspension for injection into the muscle of the neck (for pigs) or under the skin at the base of the ear (for cattle).

What is Naxcel used for?

Naxcel is used to treat pigs and cattle that have an infection caused by certain groups of bacteria. In pigs, these infections can be respiratory tract infections such as lung infections, infections of the joints and infections affecting the general health of the pigs such as septicaemia (blood infection). In cattle, Naxcel is used to treat foot rot (an infection of the feet) and acute puerperal metritis (an infection of the womb occurring after calving) in cases where treatment with another antimicrobial has failed.

How does Naxcel work?

The active substance in Naxcel is ceftiofur, which belongs to a class of antibiotics called "third generation cephalosporins". All these cephalosporin antibiotics, including ceftiofur, kill bacteria by disrupting the building of the bacterial cell walls. Like other antibiotics, ceftiofur is only effective against certain types of bacteria.

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How has Naxcel been studied?

Data from laboratory studies with different bacteria showed that ceftiofur is effective against bacteria involved in causing the pig and cattle diseases listed above.

Naxcel has been investigated in pigs with respiratory diseases caused by various bacteria or in pigs suffering from severe lameness, fever or other clinical signs of septicaemia, polyarthritis (inflammation of the joints) or polyserositis (inflammation of the internal body membranes) associated with *Streptococcus suis* infection. In these trials, Naxcel was either used on its own or compared with another authorised antibiotic (amoxicillin) or with placebo (a dummy treatment without any active substance).

In cattle, Naxcel was given under the skin at the base of the ear. The efficacy of the treatment with Naxcel was compared with the results seen in another group of cattle that were treated with ceftiofur hydrochloride.

What benefit has Naxcel shown during the studies?

In all studies, Naxcel was at least as effective as the comparator antibiotic.

What is the risk associated with Naxcel?

The most common side effects noted during the studies were local swelling and other mild reactions at the injection site (skin discoloration or small cysts). These effects disappeared after a few weeks and did not require any further treatment.

Ceftiofur (like other cephalosporins or penicillins) may cause allergic reaction in humans or in animals, which may occasionally be serious. It should, therefore, not be used in animals that have previously shown an allergy to any cephalosporin or penicillin-type antibiotics. It should also not be used in animals which may be hypersensitive to any of the ingredients.

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. Naxcel should therefore not be handled by anyone who is hypersensitive (allergic) to these antibiotics, or by anyone who has been advised not to work with them.

Naxcel should be handled with care and all of the recommended precautions be taken to avoid exposure to the product. If any symptoms occur after accidental exposure to Naxcel, 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.

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

In pigs, the withdrawal period in meat and offal is 71 days.

In cattle, the withdrawal period in meat and offal is nine days, and in milk it is zero days. However, these withdrawal periods in cattle are only valid when Naxcel has been injected under the skin in non-edible tissue at the recommended location (the base of the ear).

Why has Naxcel been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Naxcel were greater than any risks when used as recommended. The Committee therefore recommended that Naxcel should be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Naxcel:

The European Commission granted a marketing authorisation valid throughout the European Union for Naxcel on 19 May 2005. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on: 04-2013.