European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
NAXCEL

International Non-proprietary Name (INN):
Ceftiofur

On 15 July 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to extent the marketing authorisation for the veterinary medicinal product Naxcel. The Applicant for this veterinary medicinal product is Pfizer Limited, UK.

Naxcel is currently authorised as suspension for injection for pigs. The extension concerns a new target species, cattle.

The active substance of Naxcel is Ceftiofur, a third generation cephalosporin.

The new presentation will be available as 200 mg/ml suspension for injection and is to be administered subcutaneously as a single dose of 6.6 mg ceftiofur/kg bodyweight at the base of the ear.

The most common side effects are visible swellings at the injection site, which usually resolve without treatment within approximately 3 weeks.

The withdrawal period for meat and offal is 9 days and for milk zero days. It is essential that the product is only administered in non-edible tissue at the base of ear, in order to comply with the withdrawal periods.

The approved indication is: "Treatment of acute interdigital necrobacillosis in cattle, also known as *Panaritium* or foot rot".

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Naxcel and therefore recommends the extension of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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