6 May 2011
EMA/CVMP/139944/2011
Committee for Medicinal Products for Veterinary Use

Post-authorisation summary of opinion*

Naxcel

International non-proprietary name (INN): Ceftiofur

On 5 May 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Naxcel. The marketing authorisation holder for this veterinary medicinal product is Pfizer Limited.

The change agreed by the CVMP concerns a new indication: Treatment of acute post-partum (puerperal) metritis in cattle.

As ceftiofur is a third generation cephalosporin, the product should only be used where treatment with other antibiotics has failed, in line with the CVMP's strategy on antimicrobial resistance.

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SPC) which will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation/extension to the marketing authorisation has been granted by the European Commission.

* Summaries of opinion are published without prejudice to the Commission Decision.
** Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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