17 March 2017
EMA/CVMP/129619/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

ZACTRAN

International non-proprietary name (INN): gamithromycin

On 16 March 2017, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the marketing authorisation for the veterinary medicinal product Zactran. The applicant for this veterinary medicinal product is MERIAL.

Zactran is currently authorised for use in cattle and pigs. The extension concerns the addition of a new food-producing target animal species, sheep, for the following indication: "For the treatment of infectious pododermatitis (foot rot) associated with virulent *Dichelobacter nodosus* and *Fusobacterium necrophorum* requiring systemic treatment."

The most common adverse reactions in sheep are transient injection site swellings.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the extension to 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-risk balance for Zactran and therefore recommends the granting of the extension to the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] 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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