11 December 2015
EMA/CVMP/749682/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

ZACTRAN

International non-proprietary name (INN): Gamithromycin

On 10 December 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product ZACTRAN. The marketing authorisation holder for this veterinary medicinal product is MERIAL.

ZACTRAN is currently authorised as a solution for injection for subcutaneous use for cattle.

The extension is to add a new food-producing target animal species (pigs), for the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida,* and *Haemophilus parasuis*.

ZACTRAN is to be administered intramuscularly at a single dose of 6 mg gamithromycin/kg body weight in pigs. The withdrawal period in pigs is 16 days (meat and offal). Common adverse reactions in pigs are mild to moderate transient injection site swelling, which typically resolve within 2 days.

Detailed conditions for the use of this product are described in the updated 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.

[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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