13 February 2015
EMA/CVMP/102337/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Zuprevo

International non-proprietary name (INN): Tildipirosin

Procedure No. EMEA/V/C/002009/II/0006/G

On 12 February 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted an opinion[2] recommending the granting of a grouped variation to the terms of the marketing authorisation for the veterinary medicinal product Zuprevo. The marketing authorisation holder for this veterinary medicinal product is INTERVET INTERNATIONAL B.V.

The changes agreed by the CVMP concern:

The addition of a new therapeutic indication for metaphylactic use in section 4.2: "Treatment and metaphylaxis of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida, Bordetella bronchiseptica* and *Haemophilus parasuis* sensitive to tildipirosin. The presence of the disease in the herd should be confirmed before metaphylaxis is implemented".

The deletion of a warning in section 4.5: "The safety in piglets less than 4 weeks of age has not been established. Use in young piglets only according to the benefit-risk assessment by the responsible veterinarian."

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 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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