11 March 2011
EMA/CVMP/91406/2011
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Zuprevo

Tildipirosin

On 8 March 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[2] recommending the granting of a marketing authorisation for the veterinary medicinal product Zuprevo, a solution for injection for pigs and cattle, available in two different strengths. The applicant for this veterinary medicinal product is Intervet International BV.

The active substance of Zuprevo is tildipirosin, a novel macrolide antibiotic. The benefits of Zuprevo are its efficacy in the treatment of bacterial infections in the respiratory tract in pigs and cattle. The most common side effects in the target species, pigs and cattle, are local reactions at the site of the injection. As accidental self-injection might cause serious health effects in humans, injections should be performed cautiously. The withdrawal periods for meat and offal are 9 days (pigs) and 47 days (cattle).

The approved indications are:

- Pigs: The treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Bordetella bronchiseptica* and *Haemophilus parasuis* sensitive to tildipirosin.
- Cattle: The treatment and prevention of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni* sensitive to tildipirosin. The presence of the disease in the herd should be established before preventive treatment.

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 Zuprevo and therefore recommends the granting of the marketing authorisation.

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