21 February 2020
EMA/CVMP/50678/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Tulaven

International non-proprietary name (INN): tulathromycin

On 20 February 2020, 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 Tulaven, 100 mg/ml and 25 mg/ml solution for injection for cattle, pigs and sheep. The applicant for this veterinary medicinal product is CEVA Santé Animale.

Tulaven is a medicinal product containing tulathromycin, an antibacterial for systemic use (macrolide) (ATCvet code QJ01FA94) as active substance. Macrolides are bacteriostatic acting antibiotics and inhibit essential protein biosynthesis by virtue of their selective binding to bacterial ribosomal RNA. They act by stimulating the dissociation of peptidyl-tRNA from the ribosome during the translocation process.

Tulaven is a generic of Draxxin, which has been authorised in the EU since 11 November 2003. Studies have demonstrated the satisfactory quality of Tulaven and its bioequivalence to the reference product Draxxin. A question and answer document on generic medicines can be found *here*.

The full indication is:

Cattle (100 mg/ml)

Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida, Histophilus somni* and *Mycoplasma bovis* susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment.

Treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis* susceptible to tulathromycin.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 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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Pigs (100 mg/ml and 25 mg/ml)

Treatment and metaphylaxis of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis* and *Bordetella bronchiseptica* susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. The product should only be used if pigs are expected to develop the disease within 2-3 days.

Sheep (100 mg/ml)

Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent *Dichelobacter nodosus* requiring systemic 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-risk balance for Tulaven and therefore recommends the granting of the marketing authorisation.