17 March 2017
EMA/CVMP/69359/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Zeleris

International non-proprietary name (INN): florfenicol + meloxicam

On 16 March 2017, 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 Zeleris, a solution for injection for cattle intended for therapeutic treatment of bovine respiratory disease (BRD). The applicant for this veterinary medicinal product is CEVA Santé Animale.

Zeleris is a veterinary medicinal product containing a fixed combination of florfenicol and meloxicam as active substances (ATCvet code QJ01BA99). Florfenicol is an antibiotic acting by inhibiting protein synthesis at the ribosomal level of bacteria; meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis.

The benefits of Zeleris are its efficacy in the treatment of bovine respiratory disease (BRD) associated with pyrexia, due to infection caused by *Mannheimia haemolytica*, *Pasteurella multocida* and/or *Histophilus somni* susceptible to florfenicol. Very commonly seen adverse reactions were transient reactions at the injection site following subcutaneous administration and moderate pain during injection.

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 Zeleris 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 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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