



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

9 October 2020  
EMA/CVMP/496850/2020  
Committee for Medicinal Products for Veterinary Use

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Rexxolide

International non-proprietary name (INN): tulathromycin

On 7 October 2020, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion<sup>2</sup>, recommending the granting of a marketing authorisation for the veterinary medicinal product REXXOLIDE, solution for injection for cattle, pigs and sheep. The applicant for this veterinary medicinal product is Dechra Regulatory B.V.

REXXOLIDE is an antibacterial medicinal product for systemic use containing tulathromycin, (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.

REXXOLIDE is a generic of Draxxin, which has been authorised in the EU since 11 November 2003. Studies have demonstrated the satisfactory quality of REXXOLIDE, 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

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.

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<sup>1</sup> Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.

<sup>2</sup> 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.



### Pigs

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

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 are 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 Rextolide and therefore recommends the granting of the marketing authorisation.