20 May 2016
EMA/CVMP/289817/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

DRAXXIN

International non-proprietary name (INN): tulathromycin

On 19 May 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion[2], recommending the refusal of an extension to the terms of the marketing authorisation for the veterinary medicinal product DRAXXIN. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

The scope of the extension applied for was the addition of a new food-producing target species (sheep) for the treatment of infectious pododermatitis (foot rot) associated with *Dichelobacter nodosus* and *Fusobacterium necrophorum* sensitive to tulathromycin. The proposed route of administration was intramuscular for a single dose of 2.5 mg/kg bw. The proposed withdrawal period for sheep meat and offal was 16 days.

The grounds for the negative opinion relate to remaining concerns about efficacy.

[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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