9 September 2016
EMA/CVMP/586537/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Draxxin

International non-proprietary name (INN): tulathromycin

On 8 September 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a final opinion, recommending the granting of an extension to the marketing authorisation for the veterinary medicinal product Draxxin further to a re-examination of the initial negative opinion adopted by CVMP on 19 May 2016. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

Draxxin is currently authorised for cattle and pigs. The extension concerns the addition of a new target animal species, sheep, and is intended for use in the early stages of foot rot associated with virulent *Dichelobacter nodosus*. Treatment of foot rot in sheep should be undertaken along with other flock management measures. The most adverse reactions in sheep are transient sign of discomfort following the injection.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), for which an updated version will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the extension to 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 Draxxin solution for injection for sheep, and therefore recommends the granting of the extension to the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the opinion.

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