14 October 2011
EMA/CVMP/648569/2011
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

TruScient

Dibotermin-alfa

On 13 October 2011, 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 TruScient 0.66 mg kit for implant for dogs as an osteoinductive agent for use in the treatment of long bone fractures as an adjunct to standard surgical care using open fracture reduction. The applicant for this veterinary medicinal product is Pfizer Limited.

The active substance of TruScient is dibotermin-alfa, a bone morphogenetic protein ATCvet code QM05BC01.

The benefits of TruScient are its ability to promote new bone growth and enhance the natural healing of fractured bone as evidenced by a reduction in time to radiographic bone union. The approved indication is: *Treatment of diaphyseal fractures as an adjunct to standard surgical care using open fracture reduction in dogs*.

The following adverse reactions have been observed in laboratory studies in dogs: heterotopic ossification of the surrounding tissues; exuberant bone formation at the site of placement and ectopic bone formation; excessive bone and fluid filled cysts that remodel into normal bone over time; and, swelling at the site of placement has been observed by 2-3 weeks post surgery. Similar adverse reactions, dominated by lameness and local reactions were observed in a field study.

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 to risk balance for TruScient 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 within 90 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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