9 November 2012
EMA/670976/2012
Committee for Medicinal Products for Veterinary Use

Summary of opinion*

Kexxtone

International non-proprietary name (INN): monensin

On 8 November 2012, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion**, recommending the granting of a marketing authorisation for the veterinary medicinal product Kexxtone, 32.4 g (32.35 g), a continuous release intraruminal device, intended for the reduction in the incidence of ketosis in the peri-parturient dairy cow/heifer which is expected to develop ketosis. The applicant for this veterinary medicinal product is Eli Lilly and Company Limited.

The active substance of Kexxtone is monensin (used as sodium salt). Monensin is a polyether antibiotic from the group of carboxylic ionophores Monensin binds to bacterial cell membranes and interferes with the maintenance of important ion gradients in the cell which are needed for the transport of nutrients and to generate proton-motive force. ATC vet code: *QA16QA06*.

The benefit of Kexxtone is that it has a significant effect in the reduction in the incidence of ketosis in the peri-parturient dairy cow/heifer, which is expected to develop ketosis.

The approved indication is: "For the reduction in the incidence of ketosis in the peri-parturient dairy cow/heifer which is expected to develop ketosis".

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 Kexxtone and therefore recommends the granting of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
** 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu