EMA/776009/2012
EMEA/V/C/002235

EPAR summary for the public

Kexxtone

monensin

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

What is Kexxtone?

Kexxtone is a veterinary medicine that contains the active substance monensin. It is available as a continuous-release intraruminal device (a device administered through the animal's mouth and placed within the rumen, or first stomach, of cattle). Continuous release means that monensin is released slowly from the device.

What is Kexxtone used for?

Kexxtone is used to reduce the incidence of ketosis in dairy cows and heifers which are expected to develop ketosis in the period around calving. Ketosis is a metabolic disturbance in which blood glucose levels are low and substances called ketones (such as acetoacetatic acid and β-hydroxybutyrate) accumulate in the blood.

A single intraruminal device is given to a dairy cow or heifer three to four weeks before the expected calving, using an appropriate administration tool.

How does Kexxtone work?

The active substance in Kexxtone, monensin, is an antibiotic produced by natural fermentation. It attaches to the surface of bacterial cells and interferes with the mechanism for transporting nutrients. It is mainly active against Gram-positive bacteria. Monensin changes the population of microbes in the

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

An agency of the European Union

rumen resulting in an increase of the bacteria that produce propionate, a substance used to make glucose. This improves energy production in the cow's body and reduces the level of ketones in the blood.

How has Kexxtone been studied?

Kexxtone has been studied in one main study involving 1,312 commercial dairy cows. A single dose of Kexxtone was compared with a placebo (dummy treatment) given three to four weeks before the expected calving date. The main measure of effectiveness was the cumulative rate of clinical ketosis in the cows over the 15 to 16 weeks after calving. Clinical ketosis was defined based on a minimum level of the substance ß-hydroxybutyrate in the blood in combination with one or more clinical signs of ketosis.

What benefit has Kexxtone shown during the studies?

The cumulative ketosis rate was 11.5% in the Kexxtone group compared with 25.6% in the placebo group.

What is the risk associated with Kexxtone?

Treated cattle should be held in a confined area for one hour after administration to observe for failure to swallow or regurgitation. If this occurs, the product should be re-administered if undamaged. If damaged a new intraruminal device should be used. Cattle should be re-checked for up to four days after dosing in case the intraruminal device has not been fully swallowed and has lodged in the oesophagus (the gullet or tube leading from the mouth to the rumen). Accidental administration of more than one intraruminal device could result in side effects typical of monensin overdose, including decreased appetite, scouring (diarrhoea) and lethargy.

Kexxtone must not be used in animals weighing less than 300 kg.

Dogs, horses, other equines or guinea fowl must not be allowed access to Kexxtone as consumption of intraruminal device contents can be fatal in these species.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

Exposure to monensin may result in an allergic response in certain people. People who are known to be hypersensitive (allergic) to monensin or any of the ingredients should avoid contact with the product. The person administering Kexxtone should wear gloves when handling the product, including when retrieving a regurgitated intraruminal device. Gloves should be removed and hands and exposed skin washed after handling the product. People should not eat, drink or smoke while handling Kexxtone.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat or milk used for human consumption. The withdrawal period for Kexxtone for cattle is zero days for meat and milk.

Why has Kexxtone been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Kexxtone exceed the risks for the approved indication and recommended that Kexxtone be given a marketing authorisation. The benefit/risk balance may be found in the scientific discussion module of this EPAR.

Other information about Kexxtone:

The European Commission granted a marketing authorisation valid throughout the European Union, for Kexxtone on 28 January 2013. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 28 January 2013.