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The veterinary medicine Kexxtone suspended across the European Union

On 23 April 2024, the EMA's veterinary medicines committee, CVMP, completed a review recommending the suspension of the marketing authorisation of Kexxtone in the European Union.

This veterinary medicine contains the active substance monensin and it is intended for the reduction in 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 accumulate in the blood; it leads to loss of appetite and low milk production.

Kexxtone is 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, which consists of a core fitted with wings and containing a stack of 12 monensin tablets.

The review was initiated in March 2024 after a quality defect procedure showing deficiencies in the quality of Kexxtone, resulting in cases where cattle regurgitated the device while still containing undissolved monensin tablets. This resulted in increased accidental exposure, including deaths, in non-target species (dogs) as monensin is toxic to them. In addition, failures in the scheduled release of the tables from the device to the treated cattle led to concerns over lack of efficacy in those animals.

Having reviewed all available data, the CVMP concluded that the benefit-risk balance of Kexxtone is no longer positive and recommended that the marketing authorisation in the EU should be suspended until the marketing authorisation holder of Kexxtone implements corrective and preventive actions to address the quality defect. In addition, to prevent accidental exposure and minimise the risk of adverse events in non-target species, all batches of Kexxtone should be recalled from the market to veterinarian level.

Animal Healthcare Professionals should no longer use Kexxtone and consider other appropriate alternatives.

The CVMP opinion was sent to the European Commission, which endorsed it and issued a final legally binding decision on 15 May 2024.

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Information to animal healthcare professionals

- EMA recommended the suspension of the veterinary medicine Kexxtone 32.4 g continuous-release intraruminal device for cattle and the recall of all batches of Kexxtone from the market to veterinarian level.
- The Agency's recommendation is based on the available data which indicates that due to a quality defect there has been an increase in regurgitation of boluses by cattle still containing monensin tablets. This led to concerns over lack of efficacy in cattle and increased risk of accidental exposure to regurgitated Kexxtone devices by non-target species, including deaths in dogs.
- In light of the benefit-risk balance of Kexxtone no longer being positive, animal healthcare professionals should no longer use Kexxtone and consider other appropriate alternatives.

More about the medicine

Kexxtone is available as a continuous-release intraruminal device containing monensin tablets which is used to reduce the incidence of ketosis in dairy cows and heifers. Ketosis is a metabolic disturbance in which blood glucose levels are low and substances called ketones accumulate in the blood.

Kexxtone has been authorised for use in the EU since January 2013.

More about the procedure

The review of Kexxtone was initiated on 14 March 2024 at the request of the European Commission (EC) under Article 130(4) procedure of Regulation (EU) 2019/6. The EC asked the Agency to issue an opinion on whether the benefit-risk balance for Kexxtone continues to be positive.

The review was carried out by the Committee for Veterinary Medicinal Products (CVMP), the Committee responsible for the evaluation/questions concerning veterinary medicines, which adopted an opinion on this matter.

The CVMP opinion was forwarded to the European Commission, which issued a final legally binding decision on 15 May 2024 applicable in all EU Member States.