29/05/2024

Direct animal healthcare professional communication (DaHPC)

Kexxtone 32.4 g continuous-release intraruminal device for cattle (monensin): marketing authorisation suspension and market recall of all in-date batches

Dear Veterinarian and Animal Healthcare Professional,

Elanco, in agreement with the European Medicines Agency (EMA) and the HPRA, would like to inform you of the following:

Summary

- The marketing authorisation of Kexxtone has been suspended due to a quality defect which has resulted in cases where cattle regurgitated the device while it still contained monensin tablets. This resulted in increased accidental exposure, including deaths, in non-target species (dogs) and potential lack of efficacy in cattle.

- Kexxtone 32.4 g continuous-release intraruminal device for cattle has now been suspended from the EU market until Elanco implements corrective and preventive actions to address this quality defect.

- To minimise the risk of exposure to non-target species, all batches of Kexxtone will be recalled from the market. This recall will begin on 29th May 2024 to allow for manufacturing changes and additional quality control testing to be implemented.

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

Background information

Kexxtone 32.4 g continuous-release intraruminal device for cattle is a veterinary medicinal product (VMP) containing the active substance monensin. It was authorised in 2013 and is intended for the reduction in the incidence of ketosis in the peri-parturient dairy cow/heifer which is expected to develop ketosis.

Kexxtone is a controlled-release formulation of monensin sodium in tablet form which is enclosed in a polypropylene delivery device. The device is intended to be retained in the rumen for at least the duration of the approximately 95-day payout period.

Due to a change in manufacturing process, a quality defect arose that led to an increase in regurgitation of boluses by cattle that still contained 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, with a corresponding link to death in dogs. Following assessment of all available data related to this quality defect, EMA's Committee for Veterinary Medicinal Products (CVMP) recommended the suspension of the marketing authorisation for Kexxtone (EU/2/12/145/001-003) until enhanced manufacturing control testing can be identified to confirm the release rate and minimise the risk of accidental exposure in non-target species from a regurgitated bolus.

To prevent accidental exposure and minimise the risk of adverse events in non-target species, all batches of Kexxtone are being recalled from the market to veterinarian level as a precautionary

measure.

The market recall relates to <u>all in-date batches</u> of the product.

Elanco is currently working in close collaboration with the European Medicines Agency. Elanco is committed to resolving this concern to get Kexxtone back on the market given the importance of this tool to farmers and to the health and well-being of cattle.

Call for reporting

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product.

If farmers notice any side effects, even those already listed in the package leaflet for Kexxtone, or think that the medicine has not worked, please advise them to contact, in the first instance, their veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of the package leaflet, or via your national reporting system: https://www.hpra.ie/homepage/about-us/report-an-issue#. The information provided should contain at minimum the product identification number (visible on barrel) and administration date to the animal.

Company contact point

Should you have any questions or require additional information, please contact Elanco at: 01256 353131