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 batches

Dear Veterinarian and Animal Healthcare Professional,

Elanco, in agreement with the European Medicines Agency (EMA) and the Veterinary Medicines Directorate (VMD), 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 and UK 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 dd mmm 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) and the VMD recommended the suspension of the marketing authorisation for Kexxtone (EU/2/12/145/003 in NI and Vm 52127/5032 in GB) 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 the following batches of Kexxtone:

Country	Batch number	Expiration date
Great Britain and Northern Ireland	505087-1	09/08/2024
	505086-1	09/08/2024
	505090-1	11/08/2024
	505092-1	22/08/2024
	505096-1	27/08/2024
	505097-1	26/09/2024
	505155-1	11/10/2024
	505156-1	12/10/2024
	505166-1	18/11/2024
	505167-1	20/11/2024
	505179-1	20/03/2025
	505181-1	22/03/2025
	505180-1	22/03/2025
	505186-1	29/03/2025
	505187-1	30/03/2025
	505442-1	13/09/2025
	505441-1	13/09/2025
	505445-1	16/09/2025
	505456-2	03/10/2025
	505458-1	05/10/2025
	505461-1	12/10/2025
	505608-1	02/02/2026
	505616-1	16/03/2026
	505646-1	27/03/2026
	505647-1	28/03/2026
	505648-1	29/03/2026
	505650-1	30/03/2026
	505655-1	06/04/2026
	505656-1	11/04/2026
	505734-1	14/08/2026
	505738-1	17/08/2026
	505862-1	16/02/2027
	505863-1	19/02/2027
	505892-1	23/02/2027
	505891-1	23/02/2027

Elanco is currently working in close collaboration with the EMA and the VMD. 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.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine. 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