

Elanco Animal Health Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA United Kingdom

Product Recall

Kexxtone 32.4g continuous-release intraruminal device for cattle, EU/2/12/145/001-003

All in-date batches

29/05/2024

Dear Veterinarian / Pharmacist,

We wish to advise you that all in-date batches of Kexxtone 32.4g continuous-release intraruminal device for cattle are being recalled with immediate effect.

This recall is going to **veterinarian / pharmacy level.** This action has been agreed with the Health Products Regulatory Authority (HPRA).

The reason for the recall is 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.

The attached Direct animal Healthcare Professional Communication (DaHPC) provides additional information in relation to this issue.

Please immediately perform the following actions:

- 1. Quarantine any in-date units of this product which you have in your possession.
- 2. For pharmacists only, please check your dispensing records and identify prescribers of the product and forward them a copy of the attached DaHPC.
- 3. If you have supplied any other veterinarian, pharmacy, clinic or other such establishment with units of this product, please provide them with a copy of this recall letter and DaHPC, and request they quarantine and return unsold stock to you.
- 4. Contact the wholesaler from which you purchased the stock to arrange for the return of all quarantined units. The last date that stock can be accepted back for credit is 13th June 2024.

Replacement stock of this product is not available to order at this time.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Elanco at telephone number 01256 353131.

Yours sincerely,



Elanco Animal Health

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-DocuSigned by:

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Matthew Edwards

Signer Name: Matthew Edwards Signing Reason: I approve this document Signing Time: 29-May-2024 | 7:54:48 AM EDT -84D227F4D70342CB95A0B52A3FB5B3FA

Matthew Edwards

Quality Manager, Elanco Animal Health