

Product Recall

Product Names:

- Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses (50 ml vial)

SKU: 044904

Marketing authorization numbers:

MA Number	Product Name
Vm16849/5002	Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses
Vm16849/3002	Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses

Date: 17 July 2025

Dear Veterinarian/Pharmacist,

We wish to advise you that the **50 ml vial** presentation of the product below is being recalled immediately.

Batch Number	Expiry Date	Product
148221	23 May 2026	Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses (50 ml vial)
149367	09 June 2026	Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses (50 ml vial)
154100	22 January 2027	Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses (50 ml vial)
156456	25 March 2027	Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses (50 ml vial)

This recall is going to veterinarian/retailer level. The reason for the recall relates to the identification of visible particles present in the vials. To ensure animal safety, Dechra Pharmaceuticals is performing a voluntary recall of potentially impacted batches.

This action has been agreed with the Veterinary Medicines Directorate (VMD).

We would like to request that you review your inventory immediately and quarantine any units of this product you have in your possession.

We would also request that you perform a physical count of the stock (confirming correct

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Dechra Pharmaceuticals PLC. Registered Office: 24 Cheshire Avenue, Cheshire Business Park, Lostock Gralam, Northwich, CW9 7UA
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reconciliation against your system), complete the attached form and send it to the email address below.

Adminteam.uk@dechra.com Uldum.Recall@dechra.com

If any units have been found in your possession, we request these units to be returned by 22nd August 2025 via the original supply chain (i.e. return the units to the seller/supplier) to ensure credits are processed accordingly.

Please ensure the product is packed in suitable containers to avoid any damage in transit.

Note that only the 50 ml presentation is impacted by this recall.

A pharmacovigilance batch review over the past three years revealed 25 adverse event cases worldwide reporting a perceived lack of effect in 37 horses following exposure to the product "Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses". The product literature states that a small proportion of animals have been reported to be unresponsive to ketamine as an anaesthetic agent at normal doses. And while the overall number remains low relative to the volume of product used, Dechra has observed an increase in frequency for lack of efficacy reports in horses from very rare (less than 1 in 10,000 animals) to rare (1 to 10 animals in 10,000 animals) since the release of affected batches. Associated with some of these lack of efficacy reports has been the sign nystagmus, which has occurred with a very rare frequency (less than 1 in 10,000 animals). Importantly, no fatalities in horses were reported in relation to lack of efficacy, other than those related to planned euthanasia.

There has also been an increase in suspected adverse event reports received which include events such as seizures and paddling following use of affected batches. However, due to factors such as limited information provided, the administration of multiple products prior to the adverse event occurring and off-label use, we have determined that there is not currently enough information to show an association between these adverse events and the product. We will continue to closely monitor reports and to liaise with the VMD regarding all adverse events received.

Dechra would encourage any veterinarians experiencing concerns with product use and possible adverse events to contact Dechra or your local regulatory authority. For adverse event reports or any other questions, please contact Dechra at Ph. +44 1939 211 200 or via the Contact form on www.dechra.co.uk.

Thank you for your cooperation. Please contact Uldum.Recall@dechra.com if you have any inquiries related to this notification. We appreciate your immediate attention and

cooperation.

On behalf of Dechra I would like to apologize for the inconvenience this issue may have caused you and assure you that we remain committed to product quality, integrity and patient satisfaction.

Thank you for your understanding and continuous trust in Dechra.

Yours sincerely,



Rachel Martin
Country Manager

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SKU: 044904

We have reviewed our inventory (check one):

- ☐ No units were detected in our inventory
- ☐ Yes, one or more units were detected in our inventory
(if yes, please fill in information below)

Product Name & Presentation Type: Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses (50 ml vial)

<u>Lot/Batch</u>	<u>Units</u>
<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>

Company:

Address:

Phone:

Name:

Title:

Signature/Date:

E-mail: adminteam.uk@dechra.com Uldum.Recall@dechra.com

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