



Veterinary Medicines Directorate


IMPORTANT – DELIVER IMMEDIATELY Rapid Alert Notification of a Quality Defect / Recall

Reference Number: QD22/005
RapidAlert: QDefect,Class I; Recall,
UK/I/027/001

1. To: All on rapid alert notification list		
2. Product Recall Class of Defect: (circle one)	I	3. Counterfeit / Fraud (specify)* Counterfeit
4. Product: Micotil 300 mg/ml Solution for Injection	5. Marketing Authorisation Number: Vm 00879/4203 For use in animals	
6. Brand/Trade Name: Micotil Solution for Injection	7. INN or Generic Name: Tilmicosin Injection	
8. Dosage Form: Solution for Injection	9. Strength: 300mg/ml	
10. Batch number (and bulk, if different): N/A	11. Expiry Date: N/A	
12. Pack size and Presentation: 300mg/ml	13. Date Manufactured: N/A	
14. Marketing Authorisation Holder: Elanco Europe Ltd Contact Person: Delphine Laurent Telephone: +44-01256-353 131 Email: DELPHINE.LAURENT@elancoah.com		
15. Manufacturers Norbrook Laboratories Limited 105 Armagh Road Newry County Down Northern Ireland BT35 6PU Norbrook Laboratories Limited Station Works Camlough Road Newry Northern Ireland BT35 6JP		16. Recalling Firm (if different): Contact Person: Telephone:



Держпродспоживслужба
№11.1.1-5/4882 від 09.05.2022
КЕП: ШЕВЧЕНКО О. П. 09.05.2022 15:46
2B6C7DF9A3891DA1040000005C9DAA00EA041A03

17. Recall Number Assigned (if available):		
18. Details of Defect/Reason for Recall: The MAH has been made aware of something claiming to be this product being sold at local markets in the UK. No samples have been returned to the MAH for examination, but it is stated that the company logo wasn't correct and the print quality and lay out was also noticeably different. The reporter was unable to give more information (batch number or photographs) but based on the information above Elanco is confident that this product is a counterfeit.		
19. Information on distribution including exports (type of customer, e.g. hospitals): The authorised product is marketed and distributed in the UK only by wholesale dealers to veterinary clinics or directly to the vet.		
20. Action taken by Issuing Authority: Notifying of the network.		
21. Proposed Action: -		
22. From (Issuing Authority): United Kingdom, Veterinary Medicines Directorate (VMD)		23. Contact Person: rapidalert@vmd.gov.uk
24. Signed: 	25. Date: 19/04/2022	26. Time: 14:45

* Information not required, when notified from outside EU.

The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC or Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has certified the batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.

This is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorised to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorised. If you have received this document in error, please notify us by telephone immediately and return it to us at the above address by mail. Thank you.