



# Clifton Health Department Food Recall Notification



**Public Health**  
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## Food/Drug/Pet Recall: Norbrook Laboratories Limited

Norbrook Laboratories Limited of Newry, United Kingdom is recalling 34 lots of veterinary injectable drug products to the veterinarian/consumer level as a precautionary measure as product sterility cannot be assured. There is a concern that if the sterility of these products has been compromised, use of these products could result in introduction of infectious agents to the animal. This may result in the need for medical intervention(s) including, but not limited to the need for supportive care, antibiotics, and/or antifungal drugs. Intravenous administration of non-sterile drugs is especially concerning, due to the risk of rapid systemic dissemination of infectious agents, which could result in sepsis of the animal and death.

Norbrook Laboratories Limited discovered that product tested, released and distributed within the USA was manufactured on an aseptic line that subsequently did not pass process simulation tests. Norbrook places the utmost emphasis on safety and product quality at every step in the manufacturing and supply chain process. Although the possibility of a breach in sterility assurance in distributed product cannot be eliminated, no batches of product have been identified as containing microorganisms.

Enroflox® 100 Injection (enrofloxacin: 100 mg/mL) is an antimicrobial used for the treatment and control of bovine respiratory disease, for the treatment and control of swine respiratory disease, and for the control of Colibacillosis in swine.

Noromectin® Plus Injection (ivermectin: 10 mg/mL and clorsulon: 100 mg/mL) is a parasiticide used for the treatment and control of internal and external parasites in cattle.

300 PRO LA and Noromycin® 300 LA (oxytetracycline: 300 mg/mL) is a broad-spectrum antibiotic used for the treatment of a wide range of diseases caused by susceptible gram-positive and gram-negative bacteria in beef cattle, non-lactating dairy cattle, calves and swine.

Oxytetracycline Injection 200, Terra-Vet 200 and Duramycin 72-200 (oxytetracycline: 200 mg/mL) are a broad-spectrum antibiotic for use in beef cattle, dairy cattle, calves and swine.

Flunixin Injection, PrevailT and VetamegT (flunixin meglumine: 50 mg/mL) are a non-steroidal analgesic agent with anti-inflammatory and anti-pyretic activity for use in horses and cattle.

Flunixin Injection -S (flunixin meglumine: 50 mg/mL) is a non-steroidal analgesic agent with anti-inflammatory and anti-pyretic activity for use in swine.

Carprieve® Injection, CarproJectT Injection, LevafenT Injection and OstiFenT Injection (carprofen: 50 mg/mL) are a non-steroidal anti-inflammatory drug (NSAID) used for the relief of pain and inflammation associated with osteoarthritis and control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.



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Loxicom® Injection, EloxiJectT Injection and OstiLoxT Injection (meloxicam: 5 mg/mL) are a non-steroidal anti-inflammatory drug (NSAID) used for the relief of pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration in dogs and cats.

Enroflox® Injection for Dogs 2.27% and EnroSiteT Injection for Dogs 2.27% (enrofloxacin: 22.7 mg/mL) are indicated for the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

The product lots subject to recall are listed below. The product can be identified by checking the product name, manufacturer details and lot number on the carton or vial.

## NDC

Product Name

Package Size

Lot Number

Expiry Date

55529-152-02 Enroflox 100 100 mL vial 9075-90A Feb 2022  
55529-011-01 Noromectin Plus Injection 50 mL vial 9065-90A Feb 2022  
55529-014-02 300 PRO LA 100 mL vial 9063-90B Feb 2022  
55529-015-02 Noromycin 300 LA 100 mL vial 9063-90A Feb 2022  
55529-004-02 Oxytetracycline Injection 200 100 mL vial 9071-94C Feb 2022  
55529-004-02 Oxytetracycline Injection 200 100 mL vial 9071-94D Feb 2022  
55529-004-02 Oxytetracycline Injection 200 100 mL vial 9071-94E Feb 2022  
46066-007-02 Terra-Vet 200 100 mL vial 9071-94B Feb 2022  
30798-237-10 Duramycin 72-200 100 mL vial 9071-94A Feb 2022  
55529-006-02 Flunixin Injection 100 mL vial 9092-91B Feb 2022  
13985-018-02 Prevail Injection 100 mL vial 9092-91C Feb 2022  
46066-008-02 Vetameg 100 mL vial 9092-91A Feb 2022  
55529-030-02 Flunixin Injection -S 100 mL vial 9092-91D Feb 2022  
55529-131-11 Carprieve Injection 20 mL vial 9035-90C Jan 2021  
11695-6934-1 CarproJect Injection 20 mL vial 9035-90B Jan 2021  
11695-6934-1 CarproJect Injection 20 mL vial 9084-91C Feb 2021  
14043-908-20 Levafen Injection 20 mL vial 9035-90D Jan 2021  
14043-908-20 Levafen Injection 20 mL vial 9084-91B Feb 2021  
14043-908-50 Levafen Injection 50 mL vial 9035-91A Jan 2021  
13985-748-20 OstiFen Injection 20 mL vial 9035-90A Jan 2021  
13985-748-20 OstiFen Injection 20 mL vial 9084-91A Feb 2021  
55529-040-11 Loxicom Injection 20 mL vial 9102-92A Mar 2022  
11695-6925-1 EloxiJect Injection 10 mL vial 9102-91D Mar 2022  
11695-6925-2 EloxiJect Injection 20 mL vial 9102-92B Mar 2022  
13985-559-10 OstiLox Injection 10 mL vial 9102-91A Mar 2022



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- 13985-559-20 OstiLox Injection 20 mL vial 9102-92C Mar 2022
- 55529-154-02 Enroflox Injection for Dogs 2.27% 100 mL vial 9034-92A Jan 2021
- 55529-154-01 Enroflox Injection for Dogs 2.27% 50 mL vial 9034-91B Jan 2021
- 55529-154-11 Enroflox Injection for Dogs 2.27% 20 mL vial 9034-90A Jan 2021
- 55529-154-11 Enroflox Injection for Dogs 2.27% 20 mL vial 9083-93A Feb 2021
- 13985-709-20 Enrosite Injection for Dogs 2.27% 20 mL vial 9034-90B Jan 2021
- 13985-709-20 Enrosite Injection for Dogs 2.27% 20 mL vial 9034-90C Jan 2021
- 13985-709-20 Enrosite Injection for Dogs 2.27% 20 mL vial 9083-93B Feb 2021
- 13985-709-50 Enrosite Injection for Dogs 2.27% 50 mL vial 9034-91A Jan 2021

These injectable drug products were distributed nationwide in the USA to Norbrook's wholesale distributors. Norbrook Laboratories Limited is notifying its distributors by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Norbrook is arranging for return of all recalled products to the veterinarian/consumer level for a full refund. Instructions for returning recalled products are provided in the recall letter.

The FDA's Center for Veterinary Medicine recommends calling the drug company to report adverse drug experiences or product defects for FDA-approved animal products. The drug company responsible for the approved product is required to submit these reports to FDA. Contact Norbrook Laboratories Limited at 1-866-591-5777 Monday through Friday 9 am - 5 pm CST.

If you prefer to report directly to the FDA, you can submit Form FDA 1932a by following the link to the form found at <https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportProblem/ucm055305.htm> and following the instructions for emailing the completed form to FDA.

If you have a question about ADE reporting or need a paper copy of the form, contact CVM by email at [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov) or by phone at 1-888-FDA-VETS (1-888-332-8387).

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

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No action is required of local health departments at this time for any of these recalls. If any requests for assistance are received from FDA, the Public Health and Food Protection Program will contact you. For additional information regarding warnings and recalls, please click on the weblink below.

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For all recalls - <http://www.recalls.gov/recent.html>



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