

## IN THIS SECTION



## COMPANY ANNOUNCEMENT

# Norbrook Laboratories Limited Recalls Veterinary Products to Provide Sterility Assurance

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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## Summary

**Company Announcement Date:**

May 24, 2019

**FDA Publish Date:**

May 24, 2019

**Product Type:**Animal & Veterinary  
Generic Animal Drugs**Reason for Announcement:**

Product sterility cannot be assured

**Company Name:**

Norbrook Laboratories Limited

**Brand Name:**

Norbrook

**Product Description:**

Veterinary injectable drug products

## Company Announcement

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, Prevail™ and Vetameg™ (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, CarproJect™ Injection, Levafen™ Injection and OstiFen™ 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.

Loxicom® Injection, EloxiJect™ Injection and OstiLox™ 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 EnroSite™ 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.

<b>NDC</b>	<b>Product Name</b>	<b>Package Size</b>	<b>Lot Number</b>	<b>Expiry Date</b>
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

NDC	Product Name	Package Size	Lot Number	Expiry Date
11695-6925-2	EloxiJect Injection	20 mL vial	9102-92B	Mar 2022
13985-559-10	OstiLox Injection	10 mL vial	9102-91A	Mar 2022
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/ReportaProblem/ucm055305.htm>  
(<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/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) (<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).

## Company Contact Information

### Consumers:

CVM

☎ 1-888-FDA-VETS (1-888-332-8387)

✉ AskCVM@fda.hhs.gov (mailto:AskCVM@fda.hhs.gov)

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