NOROMYCIN 300 LA- oxytetracycline injection, solution
Norbrook Laboratories Limited

Approved by FDA under NADA # 141-143

Noromycin®
300 LA
(oxytetracycline injection)

ANTIBIOTIC

Each mL contains 300 mg of oxytetracycline base (equivalent to 323.5 mg of oxytetracycline dihydrate).

For Use in Beef Cattle, Non-lactating Dairy Cattle, Calves, Including Pre-ruminating (Veal) Calves and Swine.

READ ENTIRE BROCHURE CAREFULLY BEFORE USING THIS PRODUCT.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

INTRODUCTION:

Noromycin 300 LA (oxytetracycline injection) is a sterile, ready to use solution of the broad-spectrum antibiotic oxytetracycline dihydrate. Oxytetracycline is an antimicrobial agent that is effective in treatment of a wide range of diseases caused by susceptible gram-positive and gram-negative bacteria. The antibiotic activity of oxytetracyline is not appreciably diminished in the presence of body fluids, serum or exudates.

INGREDIENTS:

Noromycin 300 LA (oxytetracycline injection) is a sterile, pre-constituted solution of the broad-spectrum antibiotic oxytetracycline dihydrate. Each mL contains 300 mg of oxytetracycline base (equivalent to 323.5 mg of oxytetracycline dihydrate), 40% (v/v) glycerol formal, 10% (v/v) polyethylene glycol 200, 2.7% (w/v) magnesium oxide, 0.4% (w/v) sodium formaldehyde sulphoxylate (as a preservative) and monoethanolamine (as required to adjust pH).

INDICATIONS:

Noromycin 300 LA is intended for use in treatment for the following diseases when due to oxytetracycline-susceptible organisms:

Beef cattle, non-lactating dairy cattle, calves, including pre-ruminating (veal) calves:

Noromycin 300 LA is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., and *Histophilus* spp. Noromycin 300 LA is indicated for the treatment of infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis,* foot-rot and diphtheria caused by *Fusobacterium necrophorum;* bacterial enteritis (scours) caused by *Escherichia coli;* wooden tongue caused by

Actinobacillus lignieresii; leptospirosis caused by *Leptospira pomona;* and wound infections and acute metritis caused by strains of staphylococcal and streptococcal organisms sensitive to oxytetracycline. Also, it is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica.*

Swine:

Noromycin 300 LA is indicated in the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli;* pneumonia caused by *Pasteurella multocida;* and leptospirosis caused by *Leptospira pomona.*

In sows Noromycin 300 LA is indicated as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

PHARMACOLOGY:

Oxytetracycline is derived from the metabolic activity of the actinomycete, *Streptomyces rimosus.* Oxytetracycline is an antimicrobial agent that is effective in the treatment of a wide range of diseases caused by susceptible gram-positive and gram-negative bacteria.

The antibiotic activity of oxytetracycline is not appreciably diminished in the presence of body fluids, serum or exudates.

Studies have shown that the half-life of oxytetracycline in blood following intramuscular treatment with Noromycin 300 LA at 5 mg per pound of bodyweight is approximately 23 hours in cattle and 18 hours in swine.

Studies have shown when Noromycin 300 LA is administered once intramuscularly to cattle or swine at 9 mg per pound of bodyweight, blood oxytetracycline concentration of greater than 0.2 mcg/mL have been observed for 3 to 4 days.

Studies have shown when Noromycin 300 LA is administered once intramuscularly or subcutaneously to cattle at 13.6 mg per pound of bodyweight, blood oxytetracycline concentration of greater than 0.2 mcg/mL have been observed for at least 7 to 8 days.

DOSAGE AND ADMINISTRATION:

Beef cattle, non-lactating dairy cattle, calves, including pre-ruminating (veal) calves:

A single intramuscular or subcutaneous dosage of 13.6 mg of oxytetracycline per pound of bodyweight, Noromycin 300 LA is recommended for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica.*

At a single intramuscular or subcutaneous dose range of 9 to 13.6 mg of oxytetracycline per pound of bodyweight, Noromycin 300 LA is recommended in the treatment of the following conditions:

1. Bacterial pneumonia caused by *Pasteurella* spp (shipping fever) in calves and yearlings where retreatment is impractical due to husbandry conditions, such as cattle on range, or where their repeated restraint is inadvisable.
2. Infectious bovine kertaconjunctivitis (pink eye) caused by *Moraxella bovis.*

For other indications Noromycin 300 LA is to be administered intramuscularly, subcutaneously or intravenously at a level of 3 to 5 mg of oxytetracycline per pound of bodyweight per day. In treatment of foot-rot and advanced cases of other indicated diseases, a dosage level of 5 mg per pound of bodyweight per day is recommended. Treatment should be continued 24 to 48 hours following remission of disease signs, however, not to exceed a total of four (4) consecutive days.

If improvement is not noted within 24 to 48 hours of the beginning of treatment, diagnosis and therapy should be re-evaluated.

Do not administer intramuscularly in the neck of small calves due to lack of sufficient muscle mass.

Use extreme care when administering this product by intravenous injection. Perivascular injection or leakage from an intravenous injection may cause severe swelling at the injection site.

Swine:

A single dosage of 9 mg of oxytetracycline per pound of bodyweight administered intramuscularly is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

For the treatment of bacterial enteritis, pneumonia, and leptospirosis, administer 3 to 5 mg of oxytetracycline per pound of bodyweight per day by intramuscular injection. Treatment should be continued 24 to 48 hours following remission of disease signs; however, not to exceed a total of four (4) consecutive days. If improvement is not noted within 24 to 48 hours of the beginning of treatment, diagnosis and therapy should be re-evaluated.

For sows, administer once intramuscularly 3 mg of oxytetracycline per pound of bodyweight approximately eight (8) hours before farrowing or immediately after completion of farrowing as an aid in the control of infectious enteritis in baby pigs.

For swine weighing 25 lbs of bodyweight and under, Noromycin 300 LA should be administered undiluted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 or 5 mg/lb.

	9 mg dosage of undiluted Noromycin 300 LA	**3 or 5 mg/lb volume of diluted Noromycin 300 LA**		
Bodyweight	**9 mg/lb**	**3 mg/lb**	**Dilution***	**5 mg/lb**
5 lb	0.15 mL	0.4 mL	37.5 mg/mL	0.7 mL
10 lb	0.30 mL	0.6 mL	50 mg/mL	1.0 mL
25 lb	0.75 mL	1.0 mL	75 mg/mL	1.7 mL

*** To prepare dilutions, add one part of Noromycin 300 LA to three (3), five (5) or seven (7) parts of the sterile water, or 5% dextrose solution as indicated; the diluted product should be used immediately.**

PRECAUTIONS:

Exceeding the highest recommended level of drug per pound of bodyweight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef cattle and non-lactating dairy cattle and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Consult with your veterinarian prior to administering this product in order to determine the proper treatment required in the event of an adverse reaction. At the first sign of any adverse reaction, discontinue use of the product and seek the advice of your veterinarian. Some of the reactions may be attributable either to anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause.

Shortly after injection treated animals may have transient hemoglobinuria resulting in darkened urine.

As with all antibiotic preparations, use of this drug may result in overgrowth of non-susceptible organisms, including fungi. The absence of a favourable response following treatment, or the development of new signs or symptoms may suggest an overgrowth of non-susceptible organisms. If superinfections occur, the use of this product should be discontinued and appropriate specific therapy should be instituted.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving Noromycin 300 LA in conjunction with penicillin.

STORAGE CONDITIONS:

Store at controlled room temperature 20-25°C (68-77°F); excursions permitted 15-30°C (59-86°F). Protect from freezing. For 100 mL size: Use within 60 days of first puncture and puncture a maximum of 24 times. For 250 mL and 500 mL sizes: Use within 60 days of first puncture and puncture a maximum of 36 times. If using a needle or draw-off spike larger than 16 gauge, discard any remaining product immediately after use.

WARNINGS:

WARNINGS: Discontinue treatment at least 28 days prior to slaughter of cattle and swine.

Not for use in lactating dairy animals. Rapid intravenous administration may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Norbrook at 1-866-591-5777.

CAUTION:

Intramuscular or subcutaneous injection may result in local tissue reactions which persists beyond the slaughter withdrawal period. This may result in trim loss of edible tissue at slaughter.

Intramuscular injection in the rump area may cause mild temporary lameness associated

with swelling at the injection site. Subcutaneous injection in the neck area may cause swelling at the injection site.

ADVERSE REACTIONS:

Reports of adverse reactions associated with oxytetracycline administration include injection site swelling, restlessness, ataxia, trembling, swelling of eyelids, ears, muzzle, anus and vulva (or scrotum and sheath in males), respiratory abnormalities (labored breathing), frothing at the mouth, collapse and possibly death. Some of these reactions may be attributed either to anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause. To report a suspected adverse reaction call 1-866-591-5777.

PRESENTATION:

Noromycin 300 LA is available in 100 mL, 250 mL and 500 mL vials.

Livestock Drug - Not for Human Use.

Manufactured by:

Norbrook Laboratories Limited,
Newry, BT35 6QQ, Co. Down,
Northern Ireland.

MADE IN THE UK

U.S. Patent No. 6,110,905

U.S. Patent No. 6,310,053

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March 2023

Norbrook®

Principal Display Panel – 500 mL Carton Label

Noromycin®
300 **LA**
(oxytetracycline injection)

ANTIBIOTIC

Each mL contains 300 mg of oxytetracycline base (equivalent to 323.5 mg of oxytetracycline dihydrate).

For the treatment of disease in beef cattle, non-lactating dairy cattle, calves, including pre-ruminating (veal) calves and swine.

Caution: Federal law restricts this drug to use by or on the order of a licensed

veterinarian.

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U.S. Patent No. 6,110,905

U.S. Patent No. 6,310,053

Net Contents: 500mL

***Norbook*®**

Principal Display Panel – 500 mL Vial Label

Noromycin®
***300* LA**
(oxytetracycline injection)

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U.S. Patent No. 6,110,905

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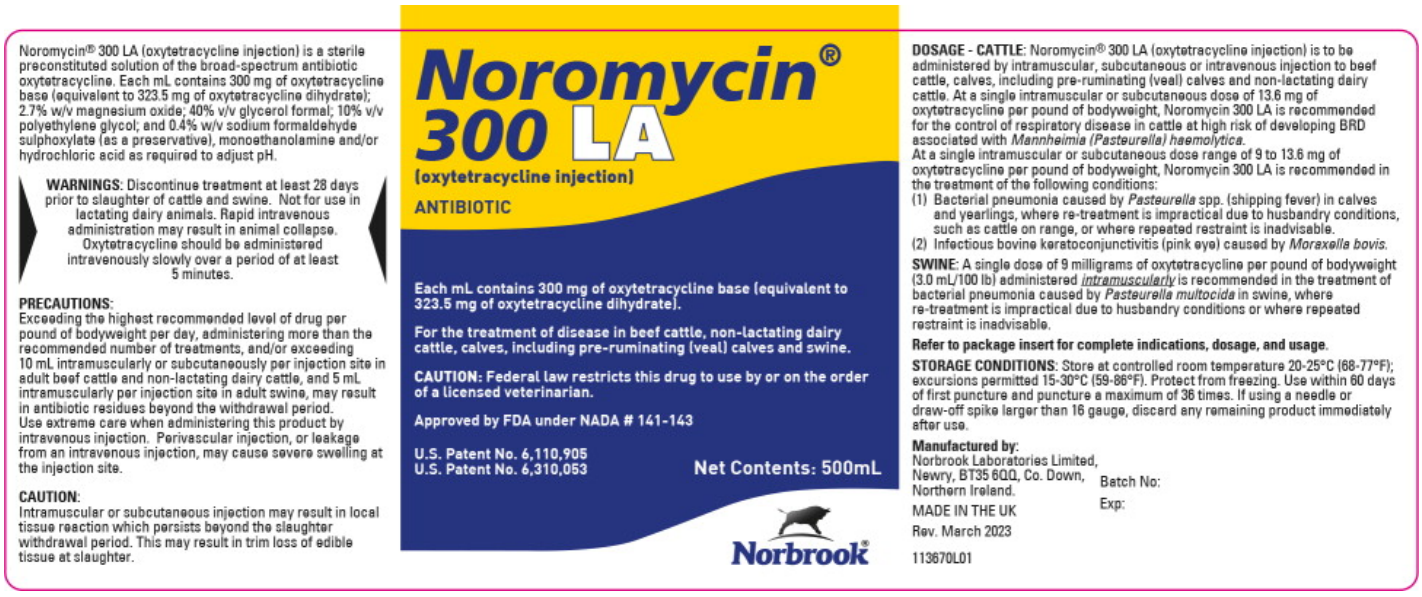
Net Contents: 500mL

Norbook®



NOROMYCIN 300 LA

oxytetracycline injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:55529-015
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
oxytetracycline (UNII: X20I9EN955) (oxytetracycline anhydrous - UNII:SLF0D9077S)	oxytetracycline	300 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
glycerol formal (UNII: 3L7GR2604E)	
polyethylene glycol, unspecified (UNII: 3WQ0SDW1A)	
magnesium oxide (UNII: 3A3U0GI71G)	
sodium formaldehyde sulfoxylate (UNII: X4ZGP7K714)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55529-015-02	1 in 1 CARTON		
1		100 mL in 1 VIAL, GLASS		
2	NDC:55529-015-04	1 in 1 CARTON		
2		250 mL in 1 VIAL, GLASS		
3	NDC:55529-015-05	1 in 1 CARTON		
3		500 mL in 1 VIAL, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141143	06/12/2023	

Labeler - Norbrook Laboratories Limited (214580029)

Establishment

Name	Address	ID/FEI	Business Operations
Norbrook Laboratories Limited		211218325	MANUFACTURE, PACK, LABEL, ANALYSIS, API MANUFACTURE

Revised: 5/2023 Norbrook Laboratories Limited