NOROMYCIN 300 LA- oxytetracycline injection, solution
Norbrook Laboratories Limited

***Noromycin 300* LA**
Oxytetracycline Injection 300 mg/mL

NADA 141-143, APPROVED BY FDA

ANTIBIOTIC

Each mL contains 300 mg of oxytetracycline base as amphoteric oxytetracycline.

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.

INTRODUCTION:

NOROMYCIN 300 LA 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.

NOROMYCIN 300 LA should be stored at room temperature 59°-86ºF (15º-30ºC). The antibiotic activity of oxytetracycline is not appreciably diminished in the presence of body fluids, serum or exudates.

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.

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.*

DOSAGE AND ADMINISTRATION:

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

A single dosage of 9 mg of oxytetracycline per pound of bodyweight administered intramuscularly or subcutaneously 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 by a veterinarian.

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.

NOROMYCIN 300 LA can also be administered by intramuscular injection at a level of 3 to 5 mg of oxytetracycline per pound of bodyweight per day. 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 by a veterinarian.

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 dosage 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.**

DIRECTIONS FOR USE:

NOROMYCIN 300 LA is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle, non-lactating dairy cattle and swine. A thoroughly cleaned, sterile needle and syringe should be used for each injection (needles and syringes may be sterilised by boiling in water for 15 minutes). In cold weather NOROMYCIN 300 LA should be warmed to room temperature before administration to animals. Before withdrawing the solution from the bottle, disinfect the rubber cap on the bottle with suitable disinfectant, such as 70 percent alcohol. The injection site should be similarly cleaned with the disinfectant. Needles of 16 to 18 gauge and 1 to 1½ inches long are adequate

for intramuscular or subcutaneous injections. Needles of 2 to 3 inches in length are recommended for intravenous use.

INTRAMUSCULAR ADMINISTRATION:

Intramuscular injections should be made by directing the needle of suitable gauge and length into the fleshy part of a thick muscle such as in the neck, rump, hip, or thigh regions; avoid blood vessels and major nerves. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site.

No more than 10 mL should be injected intramuscularly at any one site in adult beef cattle and non-lactating dairy cattle, and not more than 5 mL per site in adult swine; rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1 to 2 mL per site is injected in small calves.

SUBCUTANEOUS ADMINISTRATION:

Subcutaneous injections should be made by directing the needle of suitable gauge and length through the loose folds of the neck skin in front of the shoulder. Care should be taken to ensure that the tip of the needle has penetrated the skin but is not lodged in the muscle. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site. The solution should be injected slowly into the area between the skin and muscles. No more than 10 mL should be injected subcutaneously at any one site in adult beef cattle and non-lactating dairy cattle; rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1 to 2 mL per site is injected in small calves.

INTRAVENOUS ADMINISTRATION

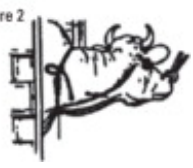
NOROMYCIN 300 LA may be administered intravenously to beef cattle and non-lactating dairy cattle. As with all highly concentrated materials, NOROMYCIN 300 LA should be administered *slowly* by the intravenous route.

Preparation of the Animal for Injection:

1. Approximate location of vein. The jugular vein runs in the jugular groove on each side of the neck from the angle of the jaw to just above the brisket and slightly above and to the side of the windpipe. (See Fig 1).
2. Restraint. A stanchion or chute is ideal for restraining the animal. With a halter, rope, or cattle leader (nose tongs), pull the animal's head around the side of the stanchion, cattle chute, or post in such a manner to form a bow in the neck (See Fig. 2), then snub the head securely to prevent movement. By forming the bow in the neck, the outside curvature of the bow tends to expose the jugular vein and make it easily accessible. Caution: Avoid restraining the animal with a tight rope or halter around the throat or upper neck which might impede blood flow. Animals that are down present no problem so far as restraint is concerned.
3. Clip hair in area where injection is to be made (over the vein in the upper third of the neck). Clean and disinfect the skin with alcohol or other suitable antiseptic.

Figure 1

Figure 2



Entering the Vein and Making the Injection:

1. Raise the vein. This is accomplished by tying the choke rope tightly around the neck close to the shoulder. The rope should be tied in such a way that it will not come loose and so that it can be untied quickly by pulling the loose end (See Fig. 2). In thick-necked animals, a block of wood placed in the jugular groove between the rope and the hide will help considerably in applying the desired pressure at the right point. The vein is a soft flexible tube through which blood flows back to the heart. Under ordinary conditions it cannot be seen or felt with the fingers. When the flow of blood is blocked at the base of the neck by the choke rope, the vein becomes enlarged and rigid because of the back pressure. If the choke rope is sufficiently tight, the vein stands out and can be easily seen and felt in thin-necked animals. As a further check in identifying the vein, tap it with the fingers in front of the choke rope. Pulsations that can be seen or felt with the fingers in front of the point being tapped will confirm the fact that the vein is properly distended. It is impossible to put the needle into the vein unless it is distended. Experienced operators are able to raise the vein simply by hand pressure, but the use of a choke rope is more certain.
2. Inserting the needle. This involves three distinct steps. First, insert the needle through the hide. Second, insert the needle into the vein. This may require two or three attempts before the vein is entered. The vein has a tendency to roll away from the point of the needle, especially if the needle is not sharp. The vein can be steadied with the thumb and finger of one hand. With the other hand the needle point is placed directly over the vein, slanting it so that its direction is along the length of the vein, either toward the head or toward the heart. Properly positioned this way, a quick thrust of the needle will be followed by a spurt of blood through the needle, which indicates that the vein has been entered. Third, once in the vein, the needle should be inserted along the length of the vein all the way to the hub, exercising caution to see that the needle does not penetrate the opposite side of the vein. Continuous steady flow of blood through the needle indicates that the needle is still in the vein. If blood does not flow continuously, the needle is out of the vein (or clogged) and another attempt must be made. If difficulty is encountered, it may be advisable to use the vein on the other side of the neck.
3. While the needle is being placed in proper position in the vein, an assistant should get the medication ready so that the injection can be started without delay after the vein has been entered.
4. Making the injection. With the needle in position as indicated by continuous flow of blood, release the choke rope by a quick pull on the free end. This is essential - the medication cannot flow into the vein while it is blocked. Immediately connect the syringe containing OXYTETRACYCLINE to the needle and slowly depress the plunger. If there is resistance to depression of the plunger, this indicates that the needle has slipped out of the vein (or is clogged) and the procedure will have to be repeated. Watch for any swelling under the skin near the needle, which would indicate that the medication is not going into the vein. Should this occur, it is best to try the vein on the opposite side of the neck.
5. Removing the needle. When injection is complete, remove needle with straight pull. Then apply pressure over area of injection momentarily to control any bleeding through needle puncture, using cotton soaked in alcohol or other suitable antiseptic.

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 time.

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:

Store at room temperature, 59-86°F (15-30°C). Keep from freezing.

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.

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.

PRESENTATION:

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

Livestock Drug - Not for Human Use. Restricted Drug(s) California. Use Only as Directed.

DISTRIBUTED BY:
Norbrook, Inc.
Lenexa, KS 66219

MADE IN THE UK

U.S. Patent No. 6,110,905
U.S. Patent No. 6,310,053

057670I03

Norbrook

Principal Display Panel – Vial Label

Noromycin 300 LA

Oxytetracycline Injection 300 mg/mL

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Each mL contains 300 mg of oxytetracycline base as amphoteric oxytetracycline.

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FOR USE IN ANIMALS ONLY

NADA 141-143, Approved By FDA

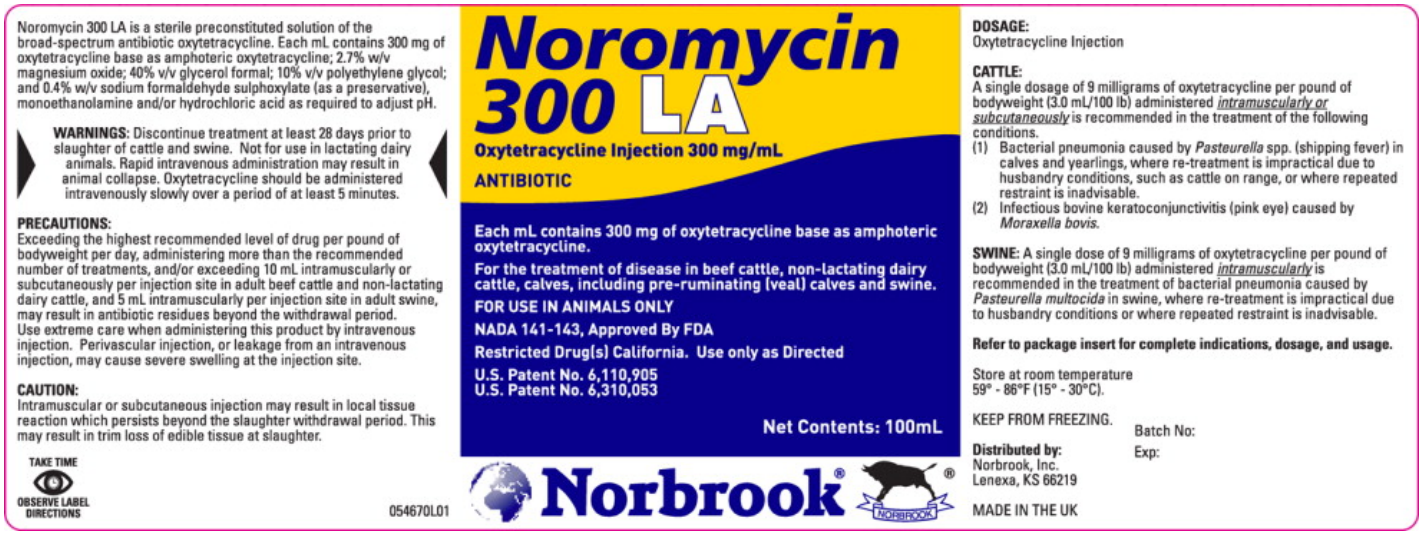
Restricted Drug(s) California. Use only as Directed

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

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

Net Contents: 100mL

Norbrook®



Principal Display Panel – Carton

Noromycin 300 LA

Oxytetracycline Injection 300 mg/mL

ANTIBIOTIC

Each mL contains 300 mg of oxytetracycline base as amphoteric oxytetracycline.

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FOR USE IN ANIMALS ONLY

NADA 141-143, Approved By FDA

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

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

Net Contents: 100mL

Norbrook®

NOROMYCIN 300 LA

oxytetracycline injection, solution

Product Information			
Product Type	OTC 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 - UNII:X20I9EN955)	oxytetracycline	300 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
glycerol formal (UNII: 3L7GR2604E)	
polyethylene glycol (UNII: 3WJQ0SDW1A)	
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	07/01/2008	

Labeler - Norbrook Laboratories Limited (214580029)

Establishment

Name	Address	ID/FEI	Business Operations
Armagh Road		232880554	MANUFACTURE, ANALYSIS

Establishment

Name	Address	ID/FEI	Business Operations
Carnbane Industrial Estate		211218325	MANUFACTURE

Revised: 9/2010 Norbrook Laboratories Limited