

300 PRO LA®

(OXYTETRACYCLINE 300 mg/mL)

R



METAPHYLAXIS

BRD

PINKEYE

FOOTROT

SCOURS

THE LONG-ACTING ANTIBIOTIC FOR BRD AND PINKEYE

300 PRO LA® - Proven Benefits At The Right Price. The Practical Treatment.

300 PRO LA® (oxytetracycline) is a versatile, broad-spectrum antibiotic available only through veterinarians. Its high cure rate and longer duration make it ideal for multiple treatment protocols including where BRD metaphylaxis is indicated. 300 PRO LA® is approved for use in beef cattle, non-lactating dairy cattle, calves, pre-ruminating (veal) calves and swine.

300 PRO LA® Offers These Advantages:

- **Long Lasting** - Studies have shown when 300 PRO LA® is administered once intramuscularly or subcutaneously to cattle at 13.6 mg per pound body weight, blood concentrations of greater than 0.2 µg/mL have been observed for at least 7 to 8 days
- **Proven** - 300 PRO LA® is a patented formulation developed by Norbrook Laboratories. This unique formulation has been proven by field use in the United States, Canada and several countries around the globe
- **Multi-Species Approval** - 300 PRO LA® is approved for use in beef cattle, non-lactating dairy cattle, calves, including pre-ruminating (veal) calves and swine
- **High Cure Rate** - Data analysis from field studies conclude this product to be effective in the control of respiratory diseases of cattle at high risk of development of BRD associated with *Pasteurella* spp.
- **Safety** - Oxytetracycline 300 PRO LA® has a proven history of safe use
- **Broad-Spectrum** - The active ingredient, oxytetracycline at 300 mg/mL, is effective against a wide range of diseases caused by susceptible gram-positive and gram-negative bacteria

300 PRO LA®

(oxytetracycline 300 mg/mL)

Cattle

Disease	Bacteria
BRD (Pneumonia, Shipping fever complex)	<i>Pasteurella</i> spp. <i>Histophilus</i> spp.
Pinkeye	<i>Moraxella bovis</i>
Scours	<i>Escherichia coli</i>
Footrot	<i>Fusobacterium necrophorum</i>
Diphtheria	<i>Fusobacterium necrophorum</i>
Leptospirosis	<i>Leptospira pomona</i>
Wooden tongue	<i>Actinobacillus lignieresii</i>
Acute metritis and wound infections	Strains of staphylococcal and streptococcal organisms sensitive to oxytetracycline

Swine

Disease	Bacteria
Bacterial enteritis (scours, colibacillosis)	<i>Escherichia coli</i>
Bacterial Pneumonia	<i>Pasteurella multocida</i>
Leptospirosis	<i>Leptospira pomona</i>
Infectious enteritis (baby pig scours, colibacillosis) in suckling pigs	<i>Escherichia coli</i>

- **Economical** - Excellent per-dose value
- **Convenient Packaging** - 100 mL, 250 mL and 500 mL bottles.

Observe label directions and withdrawal times. Not for use in lactating dairy animals. Adverse reactions, including injection site swelling, restlessness, ataxia, trembling, respiratory abnormalities (labored breathing), collapse and possibly death have been reported. See product labeling for full product information.

www.norbroominc.com

FOR VETERINARY USE ONLY

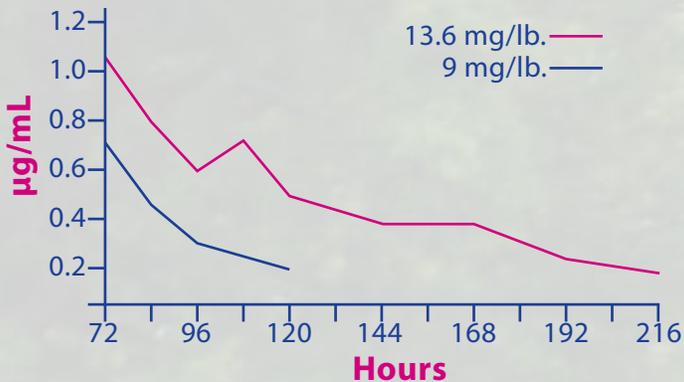
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Norbroom®

PLASMA LEVELS

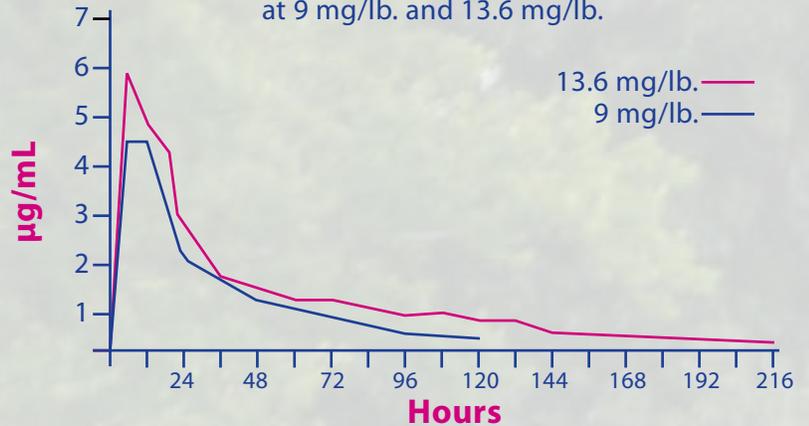
Mean Plasma Oxytetracycline Levels In Cattle

From 3 to 9 Days Post Administration of 300 PRO LA® at 9 mg/lb. and 13.6 mg/lb.



Mean Plasma Oxytetracycline Levels In Cattle

After Administration of 300 PRO LA® at 9 mg/lb. and 13.6 mg/lb.



- Rapid absorption with effective levels in less than 1 hour
- Extra-long acting, up to 8 days based upon the MIC for the bacteria associated with BRD
- Good distribution into the lungs, liver, spleen and kidneys and into body fluids such as synovial and cerebrospinal fluids

FLEXIBLE DOSAGE- CATTLE

Single IM/SQ Dose 13.6 mg/lb.	Single IM/SQ Dose 9 mg/lb. - 13.6 mg/lb.	IM/SQ/IV Dose 3 mg/lb. - 5 mg/lb.
<ul style="list-style-type: none"> • Metaphylactic use in cattle at high risk of developing BRD associated with <i>Mannheimia (Pasteurella) haemolytica</i> 	<ul style="list-style-type: none"> • Bacterial Pneumonia caused by <i>Pasteurella</i> spp. (shipping fever) • Infectious bovine keratoconjunctivitis (pinkeye) caused by <i>Moraxella bovis</i> 	<ul style="list-style-type: none"> • Scours (<i>E. coli</i>) • Diphtheria (<i>F. necrophorum</i>) • Leptospirosis (<i>L. Pomona</i>) • Wooden Tongue (<i>A. lignieresii</i>) • Acute metritis and wound infections (strains of staphylococcal and streptococcal organisms sensitive to oxytetracycline)

FLEXIBLE DOSAGE- SWINE

Single IM Dose 9 mg/lb.	Single IM Dose 3 mg/lb. - 5 mg/lb.	Single Dose (Sows Only) 3 mg/lb.
<ul style="list-style-type: none"> • Bacterial Pneumonia caused by <i>Pasteurella multocida</i> 	<ul style="list-style-type: none"> • Bacterial Enteritis (scours, colibacillosis) caused by <i>Escherichia coli</i> • Leptospirosis caused by <i>Leptospira pomona</i> 	<ul style="list-style-type: none"> • Infectious Enteritis (baby pig scours, colibacillosis) in suckling pigs caused by <i>Escherichia coli</i>

METAPHYLAXIS

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CATTLE DOSAGE GUIDE

The chart below illustrates the conversion of mg/lb. to mL's in cattle. See product label for dosage, administration and associated indications. For administration in swine, see product label.

Cattle Weight (lb.)	Number of mL's	
	9 mg/lb.	13.6 mg/lb.
100	3.0	4.5
200	6.0	9.0
300	9.0	13.6
400	12.0	18.1
500	15.0	22.6
600	18.0	27.2
700	21.0	31.7
800	24.0	36.3
900	27.0	40.8
1000	30.0	45.3
1100	33.0	49.8
1200	36.0	54.4

PRODUCT INFORMATION

- Store at room temperature (59° - 86° F)
- Withdrawal period: Discontinue treatment 28 days pre-slaughter when administered by IM, SQ or IV

ABOUT NORBROOK

Founded in 1968, Norbrook Laboratories Ltd has grown to become one of the world's leading veterinary and human pharmaceutical companies. Norbrook develops, manufactures and markets products to over 120 countries worldwide.

300
PRO LA[®]
(oxytetracycline 300 mg/mL)



300 PRO LA[®] IS AVAILABLE ONLY THROUGH VETERINARIANS

NADA 141-143, APPROVED BY FDA

300 PRO LA

(Oxytetracycline) Injection
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.

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

INTRODUCTION:

300 PRO 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.

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

INGREDIENTS:

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

INDICATIONS:

300 PRO 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:

300 PRO LA is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., and *Mycoplasma* spp. 300 PRO LA is indicated for the treatment of infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*, foot-rot and digital dermatitis 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 dermatitis 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:

300 PRO 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 300 PRO 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 300 PRO LA at 5 mg per pound of bodyweight is approximately 23 hours in cattle and 18 hours in swine.

Studies have shown when 300 PRO 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 300 PRO 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.

DOSE 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, 300 PRO 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, 300 PRO LA is recommended in the treatment of the following conditions:

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

For other indications 300 PRO 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.

300 PRO 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.

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, 300 PRO 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 300 PRO LA	3 or 5 mg/lb volume of diluted 300 PRO LA	
Bodyweight	9 mg/lb	3 mg/lb	Dilution*
5 lb	0.15 mL	0.4 mL	37.5 mg/mL
10 lb	0.30 mL	0.6 mL	50 mg/mL
25 lb	0.75 mL	1.0 mL	75 mg/mL

* To prepare dilutions, add one part of 300 PRO 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 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 300 PRO 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.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Norbrook at 1-913-589-5777.

CAUTION:

Intramuscular or subcutaneous injection may result in local tissue reactions which persist 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, diarrhea, 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:

300 PRO 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:

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Lewistown, KS 66219

MADE IN THE UK

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



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