

JAN 12 2001

Approval letter dated: \_\_\_\_\_

9407 '01 MAR HFA-305 DOCKET  
MANAGEMENT  
BRANCH

**FREEDOM OF INFORMATION SUMMARY**

**SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION**

**ANADA 200-154**

Pennox™ 200 Injectable

An injectable antibiotic for the treatment of  
bacterial diseases in swine and cattle.

Sponsored by:

Pennfield Oil Company  
14040 Industrial Road  
Omaha, Nebraska 68144

**ANADA 200-154**

**FOIS-1**

**FREEDOM OF INFORMATION SUMMARY****1. GENERAL INFORMATION:**

ANADA Number: 200-154

Original Approval Date: May 8, 1996

Sponsor: Pennfield Oil Company  
14040 Industrial Road  
Omaha, NE 68144

Generic Name: Oxytetracycline Hydrochloride, USP

Pioneer Product: Pfizer Inc., NADA 113-232, Liquamycin® LA-200

Trade Name: Pennox™ 200 Injection

Dosage Form: Injectable

How Supplied: 500 mL bottles

How Dispensed: OTC

Amount of Active Ingredients: Each ml contains 200 mg of oxytetracycline per mL

Route of Administration: Intramuscular in swine, Intramuscular, Intravenous and Subcutaneous (new) in cattle

Species: Swine, cattle, calves, including pre-ruminating (veal) calves (new)

Labeled Dosage/Indications for Use: Cattle: 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight per day for treatment of anaplasmosis, severe foot-rot, and advanced cases of other indicated diseases; 9 milligrams per pound of body weight as single dosage where retreatment for anaplasmosis is impractical; 9 milligrams per pound of body weight as a single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical; 9

milligrams per pound of body weight as a single dosage for treatment of infectious bovine keratoconjunctivitis.

Swine: 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 9 milligrams per pound of body weight as a single dosage where re-treatment for pneumonia is impractical. Sows: Administer once 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

Effect of Supplement:

The supplement provides for the addition of the subcutaneous administration of oxytetracycline injectable solution in beef cattle, non-lactating dairy cattle, and calves, including pre-ruminating (veal) calves.

## 2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). Pennfield Oil Company is supplementing their ANADA for the addition of the subcutaneous administration of oxytetracycline injectable solution in beef cattle, nonlactating dairy cattle, and calves, including pre-ruminating (veal) calves. Based upon the formulation characteristics of the generic product, Pennfield Oil Company was granted a waiver on from conducting an *in vivo* bioequivalence study with Oxyteracycline 200 Hydrochloride Injectable. The generic product was approved on May 8, 1996. The three-year exclusivity period for the additional claims granted to the pioneer product ended on April 23, 2000. Pennfield Oil Company is supplementing their approved generic product for the additional claims mentioned above. No new data was required for the additional new claims.

## 3. HUMAN FOOD SAFETY

The previous withdrawal periods and tolerances remain unchanged. Therefore, no human food safety information is required.

**4. AGENCY CONCLUSION:**

This is a Supplemental Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic (FFD&C) Act.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), these are Category II changes providing for the addition of a new route of administration and a new class of cattle. The approval of these changes is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

Attachment:

Generic and pioneer facsimile labeling

EXP. DATE:

LOT NO.:

KEEP FROM FREEZING

STORE AT ROOM TEMPERATURE 15°-30°C (59°-86°F)

cardiovascular collapse of unknown cause.

reactions may be attributed either to anaphylaxis (an allergic reaction) or to

breathing, including at the mouth, collapse and possible death. Some of these

vulva (or scrotum) and sheath in males), respiratory, abnormalities (abnormal

where repeated restraint is impractical due to husbandry conditions, or

swine. All are re-treatment is inadvisable. Refer to package insert for complete

the treatment of bacterial pneumonia caused by *Pasteurella multocida*. In

weight (4.5mL/100 lb.) administered intramuscularly is recommended in

A single dosage of 9 milligrams of oxytetracycline per pound of body

weight (4.5mL/100 lb.) administered intramuscularly is recommended in

A single dosage of 9 milligrams of oxytetracycline per pound of body

**CATTLE:**

**DOSAGE**

or subcutaneously

# Pennox 200

OXYTETRACYCLINE INJECTION

Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.

For treatment of disease in beef cattle, non-lactating dairy cattle and swine.

Net Contents: 500 mL

# PennField



ANADA 200-154; Approved by FDA

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

NOTE: intramuscularly will not be underlined

**PENNOX 200** (oxytetracycline injection) is a sterile, unpreserved solution of the broad-spectrum antibiotic, oxytetracycline. Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline and on a w/w basis: 40.0% 2-pyridone, 5.0% pyridone, 1.8% magnesium oxide, 0.2% sodium formaldehyde sulfoxylate (as a preservative), monohydrochloride and/or hydrochloric acid as required to adjust pH.

**WARNING:** Discontinue treatment at least 23 days prior to the slaughter of cattle or swine. Rapid

intravenous administration may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes.

Not for use in lactating dairy animals.

**PRECAUTIONS:** Exceeding the highest recommended level of drug per pound of body weight per day, administering more than the recommended number of treatments, and/or exceeding 1.0 mL intramuscularly per injection site in adult beef cattle and nonlactating 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 product and seek the advice of your veterinarian. Some of the reactions may be attributed either to anaphylaxis (an allergic reaction) or to cardio-vascular collapse of unknown cause.

or subcutaneously

*Distributed by:*  
**PennField Animal Health**

Omaha, NE 68114  
Not for Human Use. Use Only as Directed.  
Reinforced Drug (California)

MADE IN CROATIA

The following revisions will be inserted into the insert as noted and as follows:

1. , Calves, Including Pre-ruminating (veal) calves,
2. or subcutaneously
3. BEEF CATTLE, NON-LACTATING DAIRY CATTLE AND CALVES, INCLUDING PRE-RUMINATING (VEAL) CALVES
4. BEEF CATTLE, NON-LACTATING DAIRY CATTLE AND CALVES, INCLUDING PRE-RUMINATING (VEAL) CALVES
5. or subcutaneously
6. , calves including pre-ruminating (veal) calves,
7. SUBCUTANEOUS ADMINISTRATION: Subcutaneous injections in beef cattle, non-lactating dairy cattle and calves, including pre-ruminating (veal) calves, 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 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 1-2 mL per site is injected in small calves.

**PENNOX 200**  
(Oxytetracycline Injection)  
Antibiotic

Each mL. contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.  
For Use in Beef Cattle.  
Nonlactating Dairy Cattle and Swine ①

READ ENTIRE BROCHURE CAREFULLY BEFORE USING THIS PRODUCT.

PENNOX 200 (oxytetracycline injection) is a sterile, ready-to-use solution for the administration of the broad-spectrum antibiotic oxytetracycline by injection. 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. PENNOX 200 does not require refrigeration; however, it is recommended that it be stored at room temperature, 15°-30°C (59°-86°F). The antibiotic activity of oxytetracycline is not appreciably diminished in the presence of body fluids, serum, or exudates.

**WARNING**

↔ Discontinue treatment at least 28 days prior to the slaughter of cattle or swine. Rapid intravenous administration may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes. ↔  
Not for use in lactating dairy animals.

**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.

**PRECAUTIONS**

Exceeding the highest recommended dosage level of drug per pound of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly per injection site in adult beef cattle and nonlactating 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 product and seek the advice of your veterinarian. Some of the reactions may be attributed either to anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause. Shock may be observed following intravenous administration, especially where highly concentrated materials are involved. To minimize this occurrence, it is recommended that PENNOX 200 be administered slowly by this route. 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 nonsusceptible organisms, including fungi. A lack of response by the treated animal, or the development of new signs, may suggest that an overgrowth of nonsusceptible organisms has occurred. If any of these conditions occur, consult your veterinarian.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving PENNOX 200 in conjunction with penicillin.

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

**CARE OF SICK ANIMALS**

The use of antibiotics in the management of diseases is based on an accurate diagnosis and an adequate course of treatment. When properly used in the treatment of diseases caused by oxytetracycline-susceptible organisms, most animals that have been treated with PENNOX 200 show a noticeable improvement within 24 to 48 hours. It is recommended that the diagnosis and treatment of animal diseases be carried out by a veterinarian. Since many diseases look alike but require different types of treatment, the use of professional veterinary and laboratory services can reduce treatment time, cost and needless losses. Good housing, sanitation and nutrition are important in the maintenance of healthy animals, and are essential in the treatment of diseased animals.

**INDICATIONS**

PENNOX 200 is intended for the use in the treatment of the following diseases in beef cattle, nonlactating dairy cattle and swine when due to oxytetracycline-susceptible organisms.

**CATTLE ③**

In cattle, PENNOX 200 is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.* and *Hemophilus spp.*; infectious bovine keratoconjunctivitis (pinkeye) 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 staphylococci and streptococci organisms susceptible to oxytetracycline.

**SWINE**

In swine, PENNOX 200 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, PENNOX 200 is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

**CATTLE ④**

**DOSAGE**

PENNOX 200 is to be administered by intramuscular or intravenous injection to beef cattle and nonlactating dairy cattle.

A single dosage of 9 milligrams of PENNOX 200 per pound of body weight administered intramuscularly ⑤ is recommended in the treatment of the following conditions: (1) bacterial pneumonia caused *Pasteurella spp.* (shipping fever) in calves and yearlings, where re-treatment is impractical due to husbandry conditions, such as cattle on the range, or where their repeated restraint is inadvisable; and (2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

PENNOX 200 can also be administered by intravenous or intramuscular injection at a level of 3 to 5 milligrams of oxytetracycline per pound of body weight per day. In the treatment of severe foot-rot and advanced cases of other indicated diseases, a dosage level of 5 milligrams per pound of body weight per day is recommended. Treatment should be continued for 24 to 48 hours following remission of disease signs; however, not to exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment.

**SWINE**

In swine, a single dosage of 9 milligrams of PENNOX 200 per pound of body weight administered intramuscularly is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where re-treatment is impractical due to husbandry conditions or where repeated restraint is inadvisable. PENNOX 200 can also be administered by intramuscular injection at a level of 3 to 5 milligrams of oxytetracycline per pound of body weight per day. Treatment should be continued 24 to 48 hours following remission of disease signs; however, not to exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment.

For sows, administer once intramuscularly 3 milligrams of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after completion of farrowing.

For swine weighing 25 lb of body weight and under, PENNOX 200 should be administered undiluted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 or 5 mg/lb.

Body Weight	9 mg/lb Dosage		3 or 5 mg/lb Dosage	
	Volume of UNDILUTED PENNOX 200		Volume of DILUTED PENNOX 200	
	9 mg/lb	3 mg/lb	Dilution*	5 mg/lb
5 lb	0.2 mL	0.6 mL	1:7	1.0 mL
10 lb	0.5 mL	0.9 mL	1:5	1.5 mL
25 lb	1.1 mL	1.5 mL	1:3	2.5 mL

\*To prepare dilutions, add one part PENNOX 200 to three, five, or seven parts of sterile water, or 5 percent dextrose solution as indicated; the diluted product should be used immediately.

**DIRECTIONS FOR USE**

PENNOX 200 is intended for the use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle, nonlactating dairy cattle and swine. A thoroughly cleaned, sterile needle and syringe should be used for each injection (needles and syringes may be sterilized by boiling in water for 15 minutes). In cold weather, PENNOX 200 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 a 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 1 1/2 inches long are adequate for intramuscular injections. Needles 2 to 3 inches are recommended for intravenous use. (6)

**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 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 nonlactating 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. (7)

**INTRAVENOUS ADMINISTRATION**

PENNOX 200 (oxytetracycline injection) may be administered intravenously to beef cattle and nonlactating dairy cattle. As with all highly concentrated materials, PENNOX 200 should be administered *slowly* by the intravenous route.

**Preparation of the Animal for Injection:**

1. Approximate the location of a 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 the area where the injection is to be made (over the vein in the upper part of the neck). Clean and disinfect the skin with alcohol or other suitable antiseptic.



FIGURE 1

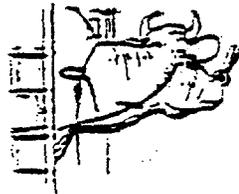


FIGURE 2

**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 become enlarged and rigid because of the back pressure. If the choke rope is sufficiently tight, the vein stands out and can easily be seen and felt in thin-necked animals. As a further check in identifying the vein, tap it 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 by the finger and thumb of one hand. With the other hand, the needle point is placed directly over the vein, slanting it so its direction is along the length of the vein, either toward the head or heart. Properly positioned this way, a quick thrust of the needle will be followed by a spurt of blood through the needle, which indicates 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. Continuously 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 injection can be started without delay after the vein has been entered.

4. Making the injection. With the needle in position as indicated by the 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 the PENNOX 200 (oxytetracycline injection) to the needle and slowly depress the plunger. If there is resistance to depression of the plunger, this indicates 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 the area of the injection momentarily to control any bleeding through needle puncture, using cotton soaked in alcohol or other suitable antiseptic.

LIVESTOCK DRUG. NOT FOR HUMAN USE  
RESTRICTED DRUG (CALIFORNIA), USE ONLY AS DIRECTED

ANADA 200-1544 Approved by FDA

Distributed By:

**PennField**   
ANIMAL HEALTH

Omaha, NE 68144

(08/00)

Made in Croatia



TAKE TIME



OBSERVE LABEL DIRECTIONS

Liquamycin LA-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline. Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline, and on a w/v basis, 40.0% 2-pyrrolidone, 5.0% povidone, 1.8% magnesium oxide, 0.2% sodium formaldehyde sulfoxylate (as a preservative), monoethanolamine and/or hydrochloric acid as required to adjust pH.

**CAUTION:** When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

**Warnings:** Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

**Precautions:** Exceeding the highest recommended level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

**Dosage:**

**Cattle:** A single dosage of 9 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) 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 repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

**Swine:** A single dose of 9 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) 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.

Refer to Package Insert for Complete Directions

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

Restricted Drug (California)—  
Use Only as Directed  
Not For Human Use

U.S. Patent No. 4,018,889



Distributed by:

**Animal Health**  
Exton, PA 19341, USA  
Div. of Pfizer Inc  
NY, NY 10017

986  
79-4984-00-1  
Made in USA

4697



# Liquamycin<sup>®</sup> LA-200<sup>®</sup> (oxytetracycline injection)

## Antibiotic

Each mL contains 200 mg  
of oxytetracycline base as  
amphoteric oxytetracycline.

For the treatment of disease in  
beef cattle; dairy cattle; calves,  
including preruminating (veal)  
calves; and swine

For animal use only

**Net Contents: 500 mL**

NADA #113-232, Approved by FDA



5  
87219 04697  
0

# Liquamycin<sup>®</sup> LA-200<sup>®</sup>

(oxytetracycline injection)

## Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.

For use in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine

For animal use only

### Read Entire Package Insert Carefully Before Using This Product

Liquamycin LA-200 (oxytetracycline injection) is a sterile, ready-to-use solution for the administration of the broad-spectrum antibiotic oxytetracycline (Terramycin<sup>®</sup>) by injection. Terramycin, discovered by Pfizer scientists, 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.

Liquamycin LA-200 administered to cattle or swine for the treatment of bacterial pneumonia at an intramuscular dosage of 9 mg of oxytetracycline per lb of body weight has been demonstrated in clinical trials to be as effective as 2 or 3 repeated, daily treatments of Terramycin Injectable at 3–5 mg/lb of body weight.

Liquamycin LA-200 does not require refrigeration; however, it is recommended that it be stored at room temperature, 15°–30°C (59°–86°F). The antibiotic activity of oxytetracycline is not appreciably diminished in the presence of body fluids, serum, or exudates.

**CAUTION:** When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

**WARNINGS:** Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

**PRECAUTIONS:** Exceeding the highest recommended dosage level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Reactions of an allergic or anaphylactic nature, sometimes fatal, have been known to occur in hypersensitive animals following the injection of oxytetracycline. Such adverse reactions can be characterized by signs such as restlessness, erection of hair, muscle trembling; swelling of eyelids, ears, muzzle, anus, and vulva (or scrotum and sheath in males); labored breathing, defecation and urination, glassy-eyed appearance, eruption of skin plaques, frothing from the mouth, and prostration. Pregnant animals that recover may subsequently abort. At the first sign of any adverse

reaction, discontinue use of this product and administer epinephrine at the recommended dosage levels. Call a veterinarian immediately.

Shock may be observed following intravenous administration, especially where highly concentrated materials are involved. To minimize this occurrence, it is recommended that Liquamycin LA-200 be administered *slowly* by this route.

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. A lack of response by the treated animal, or the development of new signs, may suggest that an overgrowth of nonsusceptible organisms has occurred. If any of these conditions occur, consult your veterinarian.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving Liquamycin LA-200 in conjunction with penicillin.

**STORAGE:** Store at room temperature 15°–30°C (59°–86°F). Keep from freezing.

**CARE OF SICK ANIMALS:** The use of antibiotics in the management of diseases is based on an accurate diagnosis and an adequate course of treatment. When properly used in the treatment of diseases caused by oxytetracycline-susceptible organisms, most animals that have been treated with Liquamycin LA-200 show a noticeable improvement within 24–48 hours. It is recommended that the diagnosis and treatment of animal diseases be carried out by a veterinarian. Since many diseases look alike but require different types of treatment, the use of professional veterinary and laboratory services can reduce treatment time, costs, and needless losses. Good housing, sanitation, and nutrition are important in the maintenance of healthy animals, and are essential in the treatment of diseased animals.

**INDICATIONS:** Liquamycin LA-200 is intended for use in the treatment of the following diseases in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine when due to oxytetracycline-susceptible organisms:

**Cattle:** Liquamycin LA-200 is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) 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 staphylococci and streptococci organisms sensitive to oxytetracycline.

**Swine:** Liquamycin LA-200 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, Liquamycin LA-200 is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

**DOSAGE:**

**Cattle:** Liquamycin LA-200 is to be administered by intramuscular, subcutaneous, or

intravenous injection to beef cattle; dairy cattle; and calves, including preruminating (veal) calves.

A single dosage of 9 mg of Liquamycin LA-200 per lb of body weight 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 keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

Liquamycin LA-200 can also be administered by intravenous, subcutaneous, or intramuscular injection at a level of 3–5 mg of oxytetracycline per lb of body weight per day. In the treatment of severe foot rot and advanced cases of other indicated diseases, a dosage level of 5 mg/lb of body weight per day is recommended. Treatment should be continued 24–48 hours following remission of disease signs; however, not to exceed a total of 4 consecutive days. Consult your veterinarian if improvement is not noted within 24–48 hours of the beginning of treatment.

**Swine:** A single dosage of 9 mg of Liquamycin LA-200 per lb of body weight 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.

Liquamycin LA-200 can also be administered by intramuscular injection at a level of 3–5 mg of oxytetracycline per lb of body weight per day. Treatment should be continued 24–48 hours following remission of disease signs; however, not to exceed a total of 4 consecutive days. Consult your veterinarian if improvement is not noted within 24–48 hours of the beginning of treatment.

For sows, administer once intramuscularly 3 mg of oxytetracycline per lb of body weight approximately 8 hours before farrowing or immediately after completion of farrowing.

For swine weighing 25 lb of body weight and under, Liquamycin LA-200 should be administered *undiluted* for treatment at 9 mg/lb but should be administered *diluted* for treatment at 3 or 5 mg/lb.

Body Weight	9 mg/lb Dosage		3 or 5 mg/lb Dosage		
	Volume of Undiluted Liquamycin LA-200		Volume of Diluted Liquamycin LA-200		
	9 mg/lb	3 mg/lb	Dilution*	5 mg/lb	
5 lb	0.2 mL	0.6 mL	1:7	1.0 mL	
10 lb	0.5 mL	0.9 mL	1:5	1.5 mL	
25 lb	1.1 mL	1.5 mL	1:3	2.5 mL	

\*To prepare dilutions, add 1 part Liquamycin LA-200 to 3, 5, or 7 parts of sterile water, or 5% dextrose solution as indicated; the diluted product should be used immediately.

**DIRECTIONS FOR USE:** Liquamycin LA-200 is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine. A thoroughly cleaned, sterile needle and syringe should be used for each injection (needles and syringes may be sterilized by boiling in water for 15 minutes). In cold weather, Liquamycin LA-200 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% alcohol. The injection site should be similarly cleaned with the disinfectant. Needles of 16–18 gauge and 1–1½ inches long are adequate for intramuscular and subcutaneous injections. Needles 2–3 inches 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 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 and 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 1–2 mL per site is injected in small calves.

**Subcutaneous Administration:**

Subcutaneous injections in beef cattle, dairy cattle, and calves, including preruminating (veal) calves, 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 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 and 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 1–2 mL per site is injected in small calves.

**Intravenous Administration:**

Liquamycin LA-200 may be administered intravenously to beef and dairy cattle. As with all highly concentrated materials, Liquamycin LA-200 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. II), 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.

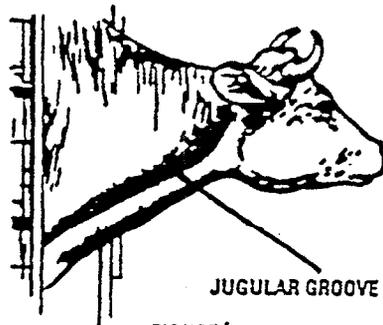


FIGURE I

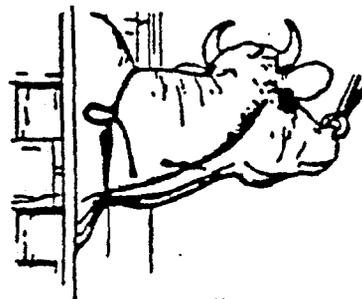


FIGURE II

#### **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. II). 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 3 distinct steps. First, insert the needle through the hide. Second, insert the needle into the vein. This may require 2 or 3 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 Liquamycin LA-200 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.

**Restricted Drug (California)—**

**Use Only as Directed**

**Not For Human Use**

NADA #113-232, Approved by FDA

TAKE TIME



OBSERVE LABEL  
DIRECTIONS



*Distributed by:*

**Animal Health**

Exton, PA 19341, USA

Div. of Pfizer Inc

NY, NY 10017

79-4984-00-1

June 1998

Printed in USA

Net Contents: 500 mL

(oxytetracycline injection)

**Liquamycin<sup>®</sup>**  
**LA-200<sup>®</sup>**

4697



Liquamycin LA-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline.

**Caution:** When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

**Warnings:** Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

**Precautions:** Exceeding the highest recommended level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Refer to Package Insert for Complete Directions

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

**Restricted Drug (California)—**  
**Use Only as Directed**

**Not for Human Use**

TAKE TIME



OBSERVE LABEL  
DIRECTIONS

Distributed by:



**Animal Health**

Exton, PA 19341, USA  
Div. of Pfizer Inc.  
NY, NY 10017

## Liquamycin<sup>®</sup> LA-200<sup>®</sup>

(oxytetracycline injection)

### Cattle Dosage Guide

At the first signs of pneumonia or pinkeye,\* administer a single dose of Liquamycin LA-200 by deep intramuscular injection, or subcutaneously, according to the following weight categories.\*\*

Animal Weight (lb)	Number of mL or cc	Animal Weight (lb)	Number of mL or cc
100	4.5	700	31.5
200	9.0	800	36.0
300	13.5	900	40.5
400	18.0	1000	45.0
500	22.5	1100	49.5
600	27.0	1200	54.0

\* See package insert for dosing instructions for other indicated diseases and full product information.

\*\* Do not administer more than 10 mL at any one injection site (1-2 mL per site in small calves).

Discontinue treatment at least 28 days prior to slaughter.

### Swine Dosage Guide

At the first signs of pneumonia,\* administer Liquamycin LA-200 by deep intramuscular injection according to the following weight categories.\*\*

Animal Weight (lb)	Number of mL or cc	Animal Weight (lb)	Number of mL or cc
10	0.5	175	7.9
25	1.1	200	9.0
50	2.3	225	10.1
75	3.4	250	11.3
100	4.5	275	12.4
125	5.6	300	13.5
150	6.8	325	14.6

\* See package insert for dosing instructions for other indicated diseases and full product information.

\*\* Do not administer more than 5 mL at any one injection site.

Discontinue treatment at least 28 days prior to slaughter.



**Liquamycin®**  
**LA-200®**  
*(oxytetracycline injection)*

4697



**Liquamycin®**  
**LA-200®**  
*(oxytetracycline injection)*

**Antibiotic**

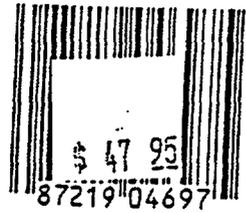
*Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.*

*For the treatment of disease in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine*

*For animal use only*

**Net Contents: 500 mL**

NADA #113-232, Approved by FDA



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LOT K9L00911  
EXP 1 SEP 02