

Reserv HFV-199 102

Date of Approval Letter: DEC 28 2001

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-123

MAXIM - 200[®]

(Oxytetracycline)

Addition of subcutaneous route of administration for beef cattle, nonlactating dairy cattle,
and preruminating (veal) calves

Sponsored by

PHOENIX SCIENTIFIC, INC.

FOIS 2

1. GENERAL INFORMATION

- a. File Number: 200-123
- b. Applicant: Phoenix Scientific, Inc.
P. O. Box 6457
St. Joseph, Missouri 64506-0457

Drug Labeler Code: 059130
- c. Established Name: oxytetracycline injection
- d. Trade/Proprietary Name: MAXIM - 200[®]
- e. Dosage Form: Sterile injectable solution
- f. How Supplied: 100,250 and 500 mL bottles
- g. How Dispensed: OTC
- h. Amount of Active Ingredient: 200 mg/mL
- i. Route of Administration: Intramuscular in swine; subcutaneous, intramuscular, or intravenous in cattle
- j. Species: Beef cattle, non-lactating dairy cattle, preruminating (veal) calves, and swine
- k. Recommended Dose: For Cattle: 3-5 mg/lb body weight IM, SC, or IV once daily for up to 4 days, or 9 mg/lb IM or SC
- l. Pharmacological Category: Antimicrobial
- m. Indications: In cattle, it is indicated for 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.

In swine, it is indicated for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. In sows, it is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

n. Pioneer Product/
"Listed" Product:

LIQUAMYCIN[®] LA-200; oxytetracycline injection; NADA # 113-232; Pfizer

o. Effect of Supplement:

To add subcutaneous route of administration for cattle.

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 (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily the ANADA sponsor shows that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc., was granted a waiver (letter dated May 20, 1992) from conducting an *in vivo* bioequivalence study for oxytetracycline injection. The generic and pioneer products contain the same active and inactive ingredients and are parenteral solutions.

3. **HUMAN FOOD SAFETY:**

• **Tolerances for Residues:**

The tolerances established for the pioneer product apply to the generic product. Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, beef calves, nonlactating dairy cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, of 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney under 21 CFR 556.500.

• **Withdrawal Time:**

Under the CVM Bioequivalence Guidelines, when a generic product is granted a waiver of *in vivo* bioequivalence testing, the withdrawal period established for the pioneer product is also assigned to the generic product.

For MAXIM - 200[®], oxytetracycline injection, a withdrawal period of 28 days has been established for beef cattle, nonlactating dairy cattle, preruminating (veal) calves, and swine (21 CFR 522.1660).

• **Regulatory Method for Residues:**

The analytical method for detection of MAXIM - 200[®] in tissues is the cylinder plate microbiological test using *Bacillus cereus* var. *mycoides* (ATCC 11778) as outlined in, the "Antibiotic Residues in Milk, Dairy Products and Animal Tissues: Methods, Reports, and Protocols" October 1968, National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 26204.

4. **AGENCY CONCLUSIONS:**

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that **MAXIM - 200[®]** when used under the proposed conditions of use, is safe and effective for its labeled indications.

5. **ATTACHMENTS:**

1. Facsimile bottle label and insert for MAXIM - 200[®], oxytetracycline injection 200 mg/mL, 100,250 and 500 mL bottles
2. Labeling: Pfizer LIQUAMYCIN LA-200[®] oxytetracycline injection 200 mg/mL, 100,250, and 500 mL bottles



should be comma (,)

MAXIM-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), monobanolate and/or hydrochloric acid as required to adjust pH.

WARNING: 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.

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 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.

Lot No.
Exp. Date

NDC 59130-445-01
NET CONTENTS: 100 mL

MAXIM-200®
(Oxytetracycline Injection)
Antibiotic

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

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

ANADA 200-123, Approved by FDA
FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

AmTech®
Group Inc.

DOSAGE-CATTLE: MAXIM-200®
A single dosage of 9 milligrams of oxytetracycline per pound 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 re-treatment 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 dosage of 9 milligrams of oxytetracycline per pound 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 re-treatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Store between 15° and 30°C (59° and 86°F)
Refer to package insert for complete indications, dosage and usage.

KEEP FROM FREEZING TAKE TIME
OBSERVE LABEL DIRECTIONS

60000
T. Rev. 3-01
Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503



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MAXIM-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.

WARNING: 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.

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 10 mL intramuscularly or subcutaneously 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.

600050

Lot No.

Exp. Date

T-Rev. 2-01

NDC 59130-645-02

NET CONTENTS:
250 mL

MAXIM-200®
(Oxytetracycline Injection)
Antibiotic

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

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

ANADA 200-123, Approved by FDA

FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

AmTech®
Group, Inc.

DOSAGE-CATTLE: MAXIM-200®

A single dosage of 9 milligrams of oxytetracycline per pound 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 re-treatment 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 dosage of 9 milligrams of oxytetracycline per pound 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.

Store between 15° and 30°C (59° and 86°F)
Refer to package insert for complete indications, dosage and usage.

KEEP FROM FREEZING

TAKE TIME  OBSERVE LABEL DIRECTIONS

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St. Joseph, MO 64503

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clh 8-30-01
CM 8-31-01
RA 9-4-01
c 8/3 9-5-01

MAXIM-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, 1.6% magnesium oxide, 0.2% sodium formaldehyde sulfoxylate (as a preservative), monoethanolamine and/or hydrochloric acid as required to adjust pH.

WARNING: 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.

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 10 mL intramuscularly or subcutaneously 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.



600050
Lot No.
Exp. Date

T-Rev. 2-01

NDC 59130-645-03

NET CONTENTS:
500 mL

MAXIM-200[®]

(Oxytetracycline Injection)
Antibiotic

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

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

ANADA 200123, Approved by FDA

FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

AmTech[®]
Group, Inc.

DOSAGE-CATTLE: MAXIM-200[®]

A single dosage of 9 milligrams of oxytetracycline per pound 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 re-treatment is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*.

SWINE: A single dosage of 9 milligrams of oxytetracycline per pound 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 re-treatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Store between 15° and 30°C (59° and 86°F)
Refer to package insert for complete indications, dosage and usage.

KEEP FROM FREEZING

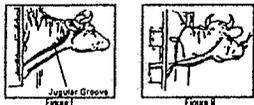
TAKE TIME  OBSERVE LABEL DIRECTIONS

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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.



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 worked quickly by pulling the loose end (See Fig. 1). In black-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 pull 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, sliding 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. Irretrievably connect the syringe containing MAXIM-200 (oxytetracycline injection) 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 the area of 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.

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DOSAGE-CATTLE: MAXIM-200®

A single dosage of 9 milligrams of oxytetracycline per pound of body weight (1.8 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 re-treatment is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*.

SWINE: A single dosage of 9 milligrams of oxytetracycline per pound 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 re-treatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Store between 15° and 30°C (59° and 86°F)
Refer to package insert for complete indications, dosage and usage.

KEEP FROM FREEZING TAKE TIME

400050

T. Rev. 2-01

Manufactured by
Phoenix Laboratories, Inc.
St. Joseph, MO 64503



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ANADA 200-123, Approved by FDA

MAXIM-200®
(oxytetracycline injection)

Antibiotic
Each mL contains 200 mg of oxytetracycline base as oxytetracycline anhydrous.

For Use in Beef Cattle, Manufacturing Dairy Cattle; Calves, including preweaning (Veal) Calves; and Swine

READ ENTIRE BROCHURE CAREFULLY BEFORE USING THIS PRODUCT
MAXIM-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. MAXIM-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 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.

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 or subcutaneously 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. 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 anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause. Shock may be observed following intravenous administration, especially with highly concentrated materials are involved. To minimize this occurrence, it is recommended that MAXIM-200 be administered slowly by this route. Short after injection, treated animals may have transient hemoglobinuria resulting in darkened urine.

As with all antibiotic preparations, use of the drug may result in overgrowth of non-susceptible organisms, including fungi. A lack of response by the least animal, or the development of new signs, may suggest that an overgrowth of non-susceptible organisms has occurred. If any of these conditions occur, consult your veterinarian.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin

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It is advisable to avoid giving MAXIM-200 in conjunction with penicillins.
STORAGE: Store between 15° and 20° C (59° and 68° F). Keep from freezing.
ADVERSE REACTIONS: Reports of adverse reactions associated with oxytetracycline administration include injection site swelling, restlessness, anaxia, trembling, swelling of eyelids, ears, muzzle, anus and vulva (or scrotum and sheath in males), respiratory abnormalities (abnormal breathing), hocking of 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.
CARE OF SICK ANIMALS: The use of antibiotics in the management of diseases is based on an accurate diagnosis and adequate course of treatment. When properly used in the treatment of diseases caused by oxytetracycline-susceptible organisms, most animals that have been treated with oxytetracycline injection 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, 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: MAXIM-200 is intended for use in the treatment of the following

diseases in beef cattle, nonlactating dairy cattle, calves, including preweaning (weal) calves; and swine when due to oxytetracycline-susceptible organisms.
CATTLE: In cattle, MAXIM-200 is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*; lock-jaw and dysphagia caused by *Proteobacterales neotrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignosus*; leptospirosis caused by *Leptospira pomona* and wound infections and acute meningitis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.
SWINE: In swine, MAXIM-200 (oxytetracycline injection) 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, MAXIM-200 is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.
DOSEAGE
CATTLE: MAXIM-200 is to be administered by intramuscular, subcutaneous or intravenous injection to beef cattle, nonlactating dairy cattle, and calves, including preweaning (weal) calves.
 A single dosage of 5 milligrams of MAXIM-200 per pound 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 re-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*.
 MAXIM-200 can also be administered by intravenous, subcutaneous 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 lock-jaw and advanced cases of other indicated diseases, dosage level of 5 milligrams per pound of body weight 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 consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment.
SWINE: In sows, a single dosage of 5 milligrams of MAXIM-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.
 MAXIM-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 5 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, MAXIM-200 should be administered undiluted for treatment at 5 mg/lb but should be administered diluted for treatment at 3.5 mg/lb body weight.

VOLUME DILUTED		VOLUME DILUTED	
MAXIM-200		MAXIM-200	
Body Weight	mg/lb	mg/lb	mg/lb
5 lb	0.2 ml	0.6 ml	1.7
10 lb	0.4 ml	0.8 ml	2.5
25 lb	1.1 ml	1.5 ml	3.8

* To prepare dilutions, add one part MAXIM-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: MAXIM-200 is intended for 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, MAXIM-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 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 or subcutaneous injections. Needles 2 to 3 inches are recommended for intravenous use.
INTRAMUSCULAR ADMINISTRATION: Intramuscular injections should be made by directing the needle at 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 40 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.
SUBCUTANEOUS ADMINISTRATION: Subcutaneous injections in beef cattle, nonlactating dairy cattle, and calves, including preweaning (weal) 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 six muscles. No more than 10 ml. should be injected subcutaneously at any one site in adult beef cattle and nonlactating dairy cattle; rotate injection sites in succeeding treatment. The volume administered per injection site should be according to age and body size so that 1 to 2 ml. per site is injected in small calves.
INTRAVENOUS ADMINISTRATION: MAXIM-200 (oxytetracycline) may be administered intravenously to beef cattle and nonlactating dairy cattle with all highly concentrated materials. MAXIM-200 should be administered slowly by the intravenous route.
Preparation of the Animal for Injection:
 1. Appropriate location on vein. The jugular vein runs in the jugular groove each side of the neck from the angle of the jaw to just above the hock, slightly above and to the side of windpipe. (See Fig. 1)
 2. Restrain. A stanchion or chute is ideal for restraining the animal. A halter, rope, or cattle leader (nose loop), put the animal's head on one side of the stanchion, cattle chute, or post in such a manner to form a T in the neck (See Fig. 2), then grab the head securely to prevent movement. Keeping the cow in the neck, the outside transverse of the bow tends to be the jugular vein and make it easily accessible. Caution: Avoid restraint animal with a tight rope or halter around the throat or upper neck might impede blood flow. Animals that are down present no problem as restraint is concerned.

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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 veins stand 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 spur 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.

- 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.
- 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 band. This is essential. The medication cannot flow into the vein while it is blocked. Immediately connect the syringe containing MAXIM-200 (oxytetracycline injection) 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.
- Removing the needle. When injection is complete, remove needle with straight pull. Then apply pressure over the area of 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.

600050
T-Rev. 2-01

DOSAGE-CATTLE: MAXIM-200®

A single dosage of 9 milligrams of oxytetracycline per pound 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 re-treatment 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 dosage of 9 milligrams of oxytetracycline per pound 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 re-treatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Store between 15° and 30°C (59° and 86°F). Refer to package insert for complete indications, dosage and usage.

KEEP FROM FREEZING

TAKE TIME TO OBSERVE LABEL DIRECTIONS

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

ANADA 200-123. Approved by FDA

MAXIM-200® (oxytetracycline injection) Antibiotic

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

For Use in Beef Cattle,
Nonlactating Dairy Cattle: Calves, including
preruminating (Veal) Calves; and Swine

READ ENTIRE BROCHURE CAREFULLY
BEFORE USING THIS PRODUCT

MAXIM-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.

MAXIM-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 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.

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 or subcutaneously 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 MAXIM-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 the drug may result in overgrowth of nonsusceptible organisms, including fungi. A lack of response by the treated animal, or the development of new lesions, 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 MAXIM-200 in conjunction with penicillin.

STORAGE: Store between 15° and 30°C (59° and 86°F). Keep from freezing.

ADVERSE REACTIONS: Reports of adverse reactions associated with oxytetracycline administration include injection site swelling, restlessness, anoxia, 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.

clh 8-30-01
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c 9-5-01

CARE OF SICK ANIMALS

The use of antibiotics in the management of diseases is based on an accurate diagnosis and adequate course of treatment. When properly used in the treatment of diseases caused by oxytetracycline-susceptible organisms, most animals that have been healed with oxytetracycline injection 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, 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

MAXIM-200 is intended for use in the treatment of the following diseases: In beef cattle, nonlactating dairy cattle, calves, including preweaning (veal) calves; and swine when due to oxytetracycline-susceptible organisms:

CATTLE

In cattle, MAXIM-200 is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; 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 rube metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

SWINE

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

DOSAGE

MAXIM-200 is to be administered by intramuscular, subcutaneous or intravenous injection to beef cattle, nonlactating dairy cattle, and calves, including preweaning (veal) calves.

A single dosage of 9 milligrams of MAXIM-200 per pound 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 re-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*.

MAXIM-200 can also be administered by intravenous, subcutaneous 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, dosage level of 5 milligrams per pound of body weight 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 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 MAXIM-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 restraints is inadvisable.

MAXIM-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, MAXIM-200 should be administered undiluted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 to 5 mg/lb body weight.

SINGLE DOSAGE		3 OR 5 MGA B DOSAGE	
VOLUME OF UN-DILUTED MAXIM-200		VOLUME OF DILUTED MAXIM-200	
Body Weight	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 MAXIM-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

MAXIM-200 is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle, nonlactating dairy cattle; calves, including preweaning (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, MAXIM-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 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 or subcutaneous injections. Needles 2 to 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 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.

SUBCUTANEOUS ADMINISTRATION

Subcutaneous injections in beef cattle, nonlactating dairy cattle, and calves, including preweaning (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. Gently 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 nonlactating 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

MAXIM-200 (oxytetracycline injection) may be administered intravenously to beef cattle and nonlactating dairy cattle. As with all highly concentrated materials, MAXIM-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 windpipe. (See Fig. I)
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 lends 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

9 mg/lb DOSAGE
Space Lowercase uppercase

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Liquamycin®
LA-200®
 (oxytetracycline injection)
Antibiotic

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

For the treatment of disease as beef cattle, dairy cattle, calves, and swine; including prurminating (veal) calves; and swine for animal use only.

Net Contents: 100 mL

NADA 113-232, Approved by FDA

06970 61228 0

74-482-002
 100 mg/mL
 100 mL

Liquamycin®
LA-200®
 (oxytetracycline injection)
Antibiotic

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

For use in beef cattle; dairy cattle; calves, including prurminating (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®) 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 nonsusceptible organisms, including fungi. A lack of response by the vealed 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 prurminating (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 prurminating (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: 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 prurminating (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*.

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Pfizer
 NADA 113-232
 Aug 1998

tiquamycin 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 Liguamycin 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.

Liguamycin 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, Liguamycin 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 Liguamycin LA-200	Volume of Diluted Liguamycin LA-200	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 Liguamycin 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: Liguamycin LA-2130 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, Liguamycin LA-200 should be warmed to room temperature before administration to animals. Before withdrawing the solution from the bottle, disinfest 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:

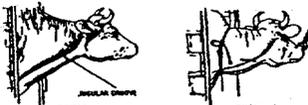
Subcutaneous injections in beef cattle, dairy cattle, and calves, including preruminating (veal) calves, should be made by directing the needle of suitable gauge and length through the loose folds of the neck skin in front of the shoulder. Care should be taken to ensure that the tip of the needle has 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:

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



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. III). 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 end 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 tiquamycin 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



Distributed by:
Animal Health

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

Aug 1998

Pfizer

NADA 113-232

Aug 1998

Liquamycin®
LA-200™
(oxytetracycline injection)

4690

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: 100 mL

NADA #113-232, Approved by FDA



104982000
986 10-4982-00-0

24x4690

Liquamycin[®]
LA-200[®]

(oxytetracycline injection)

Antibiotic

Store at room temperature 15°–30°C (59°–86°F).

Keep from freezing.

100 ml



01100872190469013024



Distributed by:

Animal Health

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

992

03-4996-00-2

Made in USA

24x4690

Liquamycin[®]
LA-200[®]

(oxytetracycline injection)

100 mL



0 87219 84690 2

UPC 87219-04690 QTY 24



01100872190469013024



Distributed by:

Animal Health

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

992

03-4982-00-2

Made in USA

4696

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: 250 ml

NADA #113-232, Approved by FDA



104983000

986 10-4983-00-0

PULL SLOWLY TO OPEN



4636



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: 250 mL

NADA #113-232, Approved by FDA



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

Manufactured by
Pfizer
Animal Health
Kalamazoo, MI 49001, USA
Div. of Pfizer Inc.
NY, NY 10017

986
79-4983-00-1
Made in USA



12x4696

Liquamycin® LA-200

(oxytetracycline injection)

Antibiotic

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

250 mL



01100872190469653012



Distributed by:

Animal Health

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

992

03-4997-00-2

Made in USA

12x4696

Liquamycin® LA-200®

(oxytetracycline injection)

250 mL



0 87219 84696 4

UPC 8721 g-04696 QTY 12



01100872190469653012



Distributed by:

Animal Health

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

992

03-4983-00-2

Made in USA

PULL SLIGHTLY TO OPEN



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 very basis, 40.0% 2-pyrrolidone, 5.0% polydextrose, 1.8% magnesium oxide, 0.2% sodium formaldehyde sulfoxylate (as a preservative), monobenzoamine and/or hydrochloric acid as required to adjust pH.

CAUTION: When administered to cattle, muscle discoloration may necessitate trimming of the injection sites 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 36 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 restraint is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pink eye) 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 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



87219 04697

Pfizer **Animal Health**
Eli Lilly and Company
New York, NY 10017
73-4984-00-1
Made in USA

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



Liquamycin® LA-200®

(oxytetracycline injection)

Cattle Dosage Guide

At the first signs of pneumonia or pink eye,* 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		1200	79.0
25	15.1	225	10.1
50	2.3	250	11.3
75	3.4	275	12.4
100	4.5	300	13.5
125	5.6	325	14.6
150	6.8		

* 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.

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

988
10-4984-00-0
Made in USA



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

Liquamycin® LA-200®

(oxytetracycline injection)



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

Caution: When administered to cattle, muscle discoloration may necessitate trimming of the injection sites and surrounding tissues during the dressing procedure.

Warnings: Discontinue treatment 28 days prior to slaughter. Do not use in milk-producing animals. Oxytetracycline is contraindicated in the treatment of calves less than 6 months of age.

Precautions: Exceeding the recommended level of administration may result in the development of bacterial resistance. Do not administer more than the recommended number of treatments and do not expect a rapid cure of or subtherapeutic injections to result in cure and dairy cattle and swine should be kept away from injection sites until the antibiotic has been completely resorbed from the injection site.

Refer to Package Insert for complete Directions.

Storage: Store at room temperature (20°-25°C/68°-77°F). Keep container dry.

Restricted Drug (California): Use Only as Directed. Not for Human Use.



Pfizer
Animal Health



0 87219 04697 5



6x4697

Liquamycini LA-200

(oxytetracycline injection)

Antibiotic

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

500 mL




01100872190469723006
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

992
03-4998-00-2
Made in USA

6x4697

Liquamycin[®] LA-200[®]

(oxytetracycline injection)

500 mL



UPC 8721 9-04697 QTY 6



01100872190469723006



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Animal Health
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Div. of Pfizer Inc
NY, NY 10017

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03-4984-00-2
Made in USA