

HFA 305

Date of Approval: JUN 13 2003

**FREEDOM OF INFORMATION SUMMARY**

**ANADA 200-128**

**Agrimycin®-200**

Indications for use: For the treatment of various bacterial diseases in cattle and swine.

**Sponsored by:**

**Agri Laboratories, Ltd.  
St. Joseph, MO 64503**

ANADA 200-128

FOIS 1

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

- a. File Number ANADA 200-128
- b. Sponsor: Agri Laboratories, Ltd.  
P.O. Box 3103  
St. Joseph, MO 64503  
Drug Labeler Code: 057561
- c. Established Name: Oxytetracycline dihydrate injection
- d. Proprietary Name: Agrimycin<sup>®</sup>-200
- e. Dosage Form: Injectable
- f. How Supplied: 100, 250 & 500 ml bottles
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Each milliliter of sterile solution contains 200 milligrams of oxytetracycline base as oxytetracycline dihydrate.
- i. Route of Administration: Intramuscularly, intravenously or subcutaneously
- j. Species/Class: Cattle and swine
- k. Recommended Dosage: Cattle:  
Administer subcutaneously or intravenously at 3 to 5 milligrams and subcutaneously at 9 milligrams of oxytetracycline per pound of body weight per day; 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

single dosage for treatment of infectious bovine keratoconjunctivitis.

Swine: administer intramuscularly at 3 to 5 milligrams of oxytetracycline per pound of body weight per day; intramuscularly at 9 milligrams per pound of body weight as a single dosage where re-treatment for pneumonia is impractical.

Sows: Administer once intramuscularly at 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

1. Pharmacological  
Category:

Antibacterial

m. Indications:

Beef cattle, dairy cattle, calves, including preruminating (veal) calves: indicated in the treatment of pneumonia and shipping fever complications 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 infection and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

Swine: 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, 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: Liquamycin<sup>®</sup> LA-200<sup>®</sup> Oxytetracycline  
Pfizer, Inc., NADA 113-232

## 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 and 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 the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. 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, Agri Laboratories, Ltd. was granted a waiver on July 5, 1991, from the requirement of an *in vivo* bioequivalence study for Agrimycin<sup>®</sup>-200 Injection. The generic and pioneer products contain the same active and similar inactive ingredients and both are parenteral solutions. The pioneer product, Liquamycin<sup>®</sup> LA-200<sup>®</sup>, the subject of Pfizer's NADA 113-232, was approved on March 14, 1980.

## 3. HUMAN SAFETY:

Tolerance for Residues:

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of beef and dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, as follows:

- (a) 2 parts per million (ppm) in muscle
- (b) 6 ppm in liver
- (c) 12 ppm in fat and kidney
- (d) 0.3 ppm in milk

### Withdrawal Time

The withdrawal times are those previously assigned to the pioneer product. The withdrawal time for oxytetracycline injection is established under 21 CFR 522.1660; 28 days for cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

### Regulatory Method for Residues

The analytical method for detection of residues of the drug is the cylinder plate microbiological test using *Bacillus cereus* var. *mycoides* (ATCC 11778) as outlined in the "Antibiotic Residues in Milk, Dairy Product and Animal Tissues: Methods, Reports, and Protocols" October 1968. National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204.

## 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 Agrimycin<sup>®</sup>-200 (oxytetracycline hydrochloride), when used under its proposed conditions of use, is safe and effective for its labeled indications.

## 5. ATTACHMENTS:

### Labeling:

Agrimycin<sup>®</sup>-200 labeling: 100, 250, 500 mL vials & insert

Liquamycin<sup>®</sup> LA-200<sup>®</sup> labeling: 250 mL vial & insert

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration  
Freedom of Information Staff (HFI-35)  
5600 Fishers Lane  
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.

AgriMycin®-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline. Each mL contains 200 mg of oxytetracycline base as oxytetracycline dihydrate, 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.

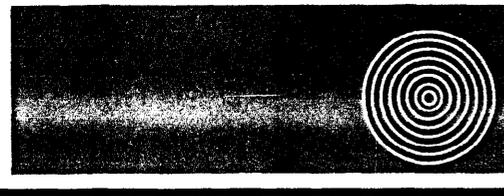
**Warnings:** Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

**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 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.

MFD. FOR AGRI LABORATORIES, LTD.  
St. Joseph, MO 64503

Issue Date 0402

Lot No.:  
Exp. Date:



## AGRIMYCIN®-200 (oxytetracycline injection)

### Antibiotic

Each mL contains 200 mg of oxytetracycline base as oxytetracycline dihydrate.  
For the treatment of disease in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine.

For animal use only.

ANADA 200-128, Approved by FDA

NET CONTENTS: 500 mL



**Dosage: Cattle:** A single dosage of 9 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered 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

TAKE TIME OBSERVE LABEL DIRECTIONS



AgriMycin®-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline. Each mL contains 200 mg of oxytetracycline base as oxytetracycline dihydrate, 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 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.

MFD. FOR AGRI LABORATORIES, LTD.  
St. Joseph, MO 64503

Lot No.:  
Exp. Date:



## AGRIMYCIN®-200 (oxytetracycline injection)

### Antibiotic

Each mL contains 200 mg of oxytetracycline base as oxytetracycline dihydrate.  
For the treatment of disease in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine.

For animal use only.

ANADA 200-128, Approved by FDA

NET CONTENTS: 250 mL



**Dosage: Cattle:** A single dosage of 9 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered 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

Issue Date 0402

TAKE TIME OBSERVE LABEL DIRECTIONS



AgriMycin®-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline. Each mL contains 200 mg of oxytetracycline base as oxytetracycline dihydrate, 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 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.

MFD. FOR AGRI LABORATORIES, LTD.  
St. Joseph, MO 64503

Lot No.:  
Exp. Date:

Issue Date 0402



## AGRIMYCIN®-200 (oxytetracycline injection)

### Antibiotic

Each mL contains 200 mg of oxytetracycline base as oxytetracycline dihydrate.  
For the treatment of disease in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine.

For animal use only.

ANADA 200-128, Approved by FDA

NET CONTENTS: 100 mL



**Dosage: Cattle:** A single dosage of 9 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered 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

Issue Date 0402



## Agrimycin®-200

(oxytetracycline injection)

### Antibiotic

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

Agrimycin-200 (oxytetracycline injection) is a sterile, ready-to-use solution for the administration of the broad spectrum antibiotic oxytetracycline by injection. Oxytetracycline, 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.

Agrimycin-200 administered to cattle or swine for the treatment of bacterial pneumonia at a 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 oxytetracycline injectable at 3-5 mg/lb of body weight.

Agrimycin-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. 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 lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL 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.

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

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

As with all antibiotic preparations, use of this drug may result in overgrowth of non-susceptible organisms, including fungi. 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 Agrimycin-200 in conjunction with penicillin.

**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 to anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause.

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

#### DOSAGE:

**Cattle:** Agrimycin-200 is to be administered by subcutaneous (SC, under the skin) or intravenous injection according to Beef Quality Assurance Guidelines.

A single dosage of 9 mg of Agrimycin-200 per lb of body weight administered 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*.

Agrimycin-200 can also be administered by subcutaneous or intravenous 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 Agrimycin-200 per lb of body weight administered intramuscularly in the neck region 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.

Agrimycin-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 in the neck region 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, Agrimycin-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 Volume of Undiluted Agrimycin-200		3 or 5 mg/lb Dosage Volume of Diluted Agrimycin-200		
	9mg/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 dilution, add 1 part Agrimycin-200 to 3, 5, or 7 parts of sterile water, or 5% dextrose solution as indicated; the diluted product should be used immediately.

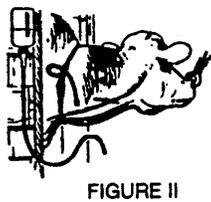
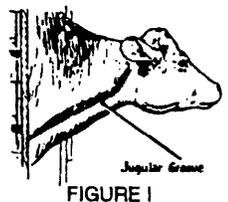
**DIRECTIONS FOR USE:** Agrimycin-200 is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine. A thoroughly cleaned, sterile needle and syringe should be used for each injection (needles and syringes may be sterilized by boiling in water for 15 minutes). In cold weather, Agrimycin-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 1-1/2 inches long are adequate for intramuscular and subcutaneous injections. Needles 2-3 inches are recommended for intravenous use.

**Intramuscular Administration:**  
Intramuscular injections in swine should be made by directing the needle of suitable gauge and length into the fleshy part of a thick muscle in the neck region; 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 5 mL should be injected at any one site in adult swine; rotate injection sites for each succeeding treatment.

**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:**  
Agrimycin-200 may be administered intravenously to beef and dairy cattle. As with all highly concentrated materials, Agrimycin-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. 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 Agrimycin-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**

ANADA 200-128, Approved by FDA



**MANUFACTURED FOR:**  
**AGRI LABORATORIES, LTD.**  
**St. Joseph, MO 64503**

**Issue Date 0402**



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 oxytetracycline dihydrate, 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 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 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 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**

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

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79-4983-00-2  
Made in USA

4696



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

### Antibiotic

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

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)

### Antibiotic

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

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®) 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 a 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. 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 lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL 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.

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

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

As with all antibiotic preparations, use of this drug may result in overgrowth of non-susceptible organisms, including fungi. 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.

**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 to anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause.

**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 subcutaneous (SC, under the skin) or intravenous injection according to Beef Quality Assurance Guidelines.

A single dosage of 9 mg of Liquamycin LA-200 per lb of body weight administered 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 subcutaneous or intravenous 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 in the neck region 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 in the neck region 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 in swine should be made by directing the needle of suitable gauge and length into the fleshy part of a thick muscle in the neck region; 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 5 mL should be injected at any one site in adult swine; rotate injection sites for each succeeding treatment.

**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. 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.



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.

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**Not For Human Use**

NADA #113-232, Approved by FDA

TAKE TIME



OBSERVE LABEL DIRECTIONS

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