FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-452

OXYTET 10 Injection
(oxytetracycline hydrochloride)

Indicated in beef cattle, beef calves, non-lactating dairy cattle and dairy calves for the treatment of the following disease conditions caused by one or more of the oxytetracycline sensitive pathogens listed as follows:
- bacterial pneumonia and shipping fever complex associated with Pasteurella spp.;
- bacterial enteritis (scours) caused by Escherichia coli;
- necrotic pododermatitis (foot rot) and calf diphtheria caused by Fusobacterium necrophorum;
- wooden tongue caused by Actinobacillus lignieresii;
- and wound infections, acute metritis and traumatic injury caused by susceptible strains of streptococcus and staphylococcus organisms.

Sponsored by
Norbrook Laboratories, Ltd.
FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number: ANADA 200-452
b. Sponsor: Norbrook Laboratories, Ltd.
   Station Works, Newry BT35 6JP,
   Northern Ireland
   Drug Labeler Code: 055529
c. Established Name: Oxytetracycline hydrochloride
d. Proprietary Name: OXYTET 10 Injection
e. Dosage Form: Injectable
f. How Supplied: 100 mL, 250 mL, & 500 mL
g. How Dispensed: OTC
h. Amount of Active Ingredients: Each mL contains 100 mg of oxytetracycline hydrochloride
i. Route of Administration: Intravenous
j. Species/Class: Beef cattle, beef calves, non-lactating dairy cattle, and dairy calves
k. Recommended Dosage: 3-5 mg/mL body weight per day for a maximum of 4 consecutive days. For intravenous administration only.
l. Pharmacological Category: Antimicrobial
m. Indications: The use of OXYTET 10 Injection is indicated in beef cattle, beef calves, non-lactating dairy cattle and dairy calves for the treatment of the following disease conditions caused by one or more of the oxytetracycline sensitive pathogens listed as follows: bacterial pneumonia and shipping fever complex associated with Pasteurella spp.; bacterial enteritis (scours) caused by Escherichia coli; necrotic pododermatitis (foot rot) and calf diphtheria caused by Fusobacterium necrophorum; wooden tongue caused by Actinobacillus lignieresii; and wound infections, acute metritis and traumatic injury caused by
susceptible strains of streptococcus and staphylococcus organisms.

n. Pioneer Product: MEDAMYCIN-100; oxytetracycline hydrochloride; NADA 108-963; Boehringer Ingelheim Vetmedica, Inc.

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 effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show 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 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 the requirement of an in vivo bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Norbrook Laboratories, Ltd. was granted a waiver from the requirement for an in vivo bioequivalence study for the generic product OXYTET 10 Injection. The generic product contains the same active and inactive ingredients in the same concentrations and dosage form as the pioneer product and is a sterile solution intended for intravenous use in cattle. The pioneer product, MEDAMYCIN-100 (oxytetracycline hydrochloride), the subject of Boehringer Ingelheim Vetmedica, Inc., under NADA 108-963, was approved on December 12, 1978.

3. HUMAN FOOD SAFETY:

- Tolerance for Residues
  The tolerances established for the pioneer product apply to the generic product. Tolerances are established for the sum of residues of tetracycline including oxytetracycline in uncooked edible tissues as follows: 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney for beef cattle, beef calves, non-lactating dairy cattle, and dairy calves (21 CFR 556.500(b)). The Acceptable Daily Intake for oxytetracycline is 25 micrograms per kilogram of body weight per day.
· **Withdrawal Time**
  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

  The withdrawal time is at least 22 days prior to slaughter.

· **Regulatory Method for Residues**
  The analytical method for the detection of residues of oxytetracycline is a microbiological test using *Bacillus cereus* var. *mycoides*. This method is found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

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 OXYTET 10 (oxytetracycline hydrochloride) Injection, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. **ATTACHMENTS:**

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

**Generic Labeling for ANADA 200-452:**
OXYTET 10 – Container Label; Box Label; Package Insert

**Pioneer Labeling for NADA 108-963:**
MEDAMYCIN-100 – Container Label; Package Insert
**OXYTET 10 INJECTION**

**Oxytetracycline Hydrochloride Injection**

**ANTIBIOTIC**

Each mL contains 100 mg Oxytetracycline HCl

For use in Beef Cattle, Beef Calves, Non-lactating Dairy Cattle and Dairy Calves Only

**DESCRIPTION**

Oxytet 10 Injection [oxytetracycline hydrochloride] is a sterile, ready-to-use preparation containing 100 mg/mL oxytetracycline hydrochloride, for administration of the broad spectrum antibiotic, oxytetracycline, by injection.

**ANTIBIOTIC ACTION OF OXYTETRACYCLINE**

Oxytetracycline is particularly effective against a wide range of gram-negative and gram-positive organisms that are pathogenic for cattle. The antibiotic is primarily bacteriostatic in effect, and is believed to exert its antibacterial action by the inhibition of microbial protein synthesis. The antibiotic activity of oxytetracycline is not appreciably diminished in the presence of body fluids, serum or exudates. Since the drugs in the tetracycline class have similar antimicrobial spectra, organisms can develop cross resistance among them. Oxytetracycline is concentrated by the liver in bile and excreted in the urine and feces at high concentrations and in a biologically active form.

**WARNING**

Discontinue treatment with Oxytet 10 Injection at 24 hours prior to slaughter of the animal. Not for use in lactating dairy animals.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

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

**CAUTION**

If no improvement occurs within 48 hours, consult a veterinarian. Do not use the drug for more than 4 consecutive days. Use beyond 4 days or doses higher than maximum recommended dose may result in antibiotic tissue residues beyond the withdrawal period.

**PRECAUTIONS**

The improper or accidental injection of the drug outside of the vein will cause local tissue irritation manifested by temporary swelling and discoloration at the injection site.

Shortly after injection, treated animals may have a transient hemoglobinuria (darkened urine). 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. Because bacteriostatic drugs interfere with the bactericidal action of penicillin, do not give oxytetracycline hydrochloride in conjunction with penicillin.

As with other antibiotics, use of this drug may result in over-growth of non susceptible organisms. If any unusual symptoms occur or in the absence of a favorable response following treatment, discontinue use immediately and call a veterinarian.

**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 (laboratory 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.

**DISEASES FOR WHICH OXYTET 10 INJECTION IS INDICATED**

The use of Oxytet 10 Injection is indicated in beef cattle, beef calves, non-lactating dairy cattle and dairy calves for treatment of the following disease conditions caused by one or more of the oxytetracycline sensitive pathogens listed as follows:

**Cassiope organisms which show sensitivity to Oxytet 10 Injection**

- Pasteurella spp.
- Escherichia coli
- Neisseria, Porphyromonas, Fusobacterium necrophorum
- Clostridium perfringens
- Mollicutes
- Actinobacillus lignieresii
- Neisseria
- Bacteroides
due to a tourniquet.

**RECOMMENDED DAILY DOSAGES**

Treat at the first clinical signs of disease.

The intravenous injection of 3 to 5 mg of oxytetracycline hydrochloride per pound of body weight per day (3 to 5 mL per 100 lb body weight) is the recommended dosage.

Severe foot-rot and severe forms of the indicated diseases should be treated with 5 mg per pound of body weight. Surgical procedures may be indicated in some forms of foot-rot or other conditions.

In disease treatment, the daily dose of Oxytet 10 Injection should be continued 24 to 48 hours following remission of disease symptoms, however, not to exceed a total of 4 consecutive days.

**DIRECTIONS FOR MAKING AN INTRAVENOUS INJECTION IN CATTLE**

Equipment recommended

1. Syringe and needles; gravity flow intravenous set. (See Fig. 1.)

2. Use new, very sharp hypodermic needles. 16-gauge, 1 to 2 inches long. dull needles will not work. Extra needles should be available in case the one being used becomes clogged.

3. Scissors or clippers.

5. 70% rubbing alcohol compound or other equally effective antiseptic for disinfecting the skin.

6. The medication to be given.

**PREPARATION OF EQUIPMENT**

Thoroughly clean the needles, syringe and intravenous set and disinfect them by building in water for twenty minutes or by immersing in a suitable chemical disinfectant such as 70% alcohol for a period of not less than 30 minutes. Warm the bottle of medication to approximate body temperature and keep warm until used.

It is recommended that the correct dose be diluted in water for injection, sodium chloride injection or other suitable vehicle immediately prior to administration. Doses up to 50 mL may be diluted in 250 mL. Larger doses may be diluted in 500 mL of one of the diluents. Adverse reactions may be minimized and the drug dose can be better regulated by this method of administration.

Avoid touching the needle with the hands at all times.

In case of the syringe method of administration, disinfect the vial cap by wiping with 70% alcohol or other suitable antiseptic. Touching a sterile needle only by the hub, attach it to the syringe and push the plunger down the barrel to empty it of air. Puncture the rubber cap of the vial and withdraw the plunger upward in the syringe to draw up a volume of Oxytet 10 Injection, 100 mg/mL, of about 5 mL more than is needed for injection. Withdraw from the vial and, pointing the needle upward, remove all air bubbles from the syringe by depressing the plunger upward to the volume required.

If the injection cannot be made immediately, the tip of the needle may be covered with cotton soaked in 70% alcohol to prevent contamination.
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 Figure 2 and 3.)

![Figure 2](image)

**Jugular Groove**

![Figure 3](image)

**Vertebrae**
**Caudate Artery**
**Carotis Artery**
**Jugular Vein**
**Jugular Groove**
**Esophagus**
**Teeth**

2. Method of restraint - A strangulation or chute is ideal for restraining the animal. With a halter, rope or cattle leader (noose rings), pull the animal's head across the side of the strangulation, chute or post in such a manner as to form a bow in the neck (see Figure 4). This will partly subdue the animal, and make it easy to secure to prevent movement. By forming the bow in the neck, the outside curvature of the bow bends to expose the jugular vein and make it easy to access. Caution: Avoid a tight rope or halter around the throat or upper neck which might impede blood flow. Animals that are down present no problem as far as restraint is concerned.

3. Cleft 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.

**DOSAGE FOR INJECTION**
Refer to the table below for proper dosage according to body weight of the animal:

<table>
<thead>
<tr>
<th>Weight of Animal, Lbs</th>
<th>Midrange of Daily Dosage of Glycerol Nitrate Hydrochloride</th>
<th>Levoathene in per 100 lbs</th>
<th>Amount of Levoathene in Lb.</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 lbs</td>
<td>500 - 600 mg</td>
<td>1.5 - 2.5 ml</td>
<td>0.5 - 1.0 Lb</td>
</tr>
<tr>
<td>75 lbs</td>
<td>750 - 900 mg</td>
<td>3 - 4 ml</td>
<td>1.5 - 2.75 Lb</td>
</tr>
<tr>
<td>100 lbs</td>
<td>1000 - 1200 mg</td>
<td>6 - 10 ml</td>
<td>3 - 5 Lb</td>
</tr>
<tr>
<td>125 lbs</td>
<td>1250 - 1500 mg</td>
<td>8 - 10 ml</td>
<td>4 - 6 Lb</td>
</tr>
<tr>
<td>150 lbs</td>
<td>1500 - 1750 mg</td>
<td>15 ml</td>
<td>7.5 Lb</td>
</tr>
<tr>
<td>175 lbs</td>
<td>1750 - 2000 mg</td>
<td>18 ml</td>
<td>9 Lb</td>
</tr>
<tr>
<td>200 lbs</td>
<td>2000 - 2400 mg</td>
<td>24 - 30 ml</td>
<td>12 Lb</td>
</tr>
<tr>
<td>225 lbs</td>
<td>2250 - 2700 mg</td>
<td>30 - 40 ml</td>
<td>15 Lb</td>
</tr>
<tr>
<td>250 lbs</td>
<td>2500 - 3000 mg</td>
<td>40 - 50 ml</td>
<td>20 Lb</td>
</tr>
<tr>
<td>275 lbs</td>
<td>2750 - 3250 mg</td>
<td>50 - 60 ml</td>
<td>25 Lb</td>
</tr>
</tbody>
</table>

CAUTION: If no improvement is noted within 30 to 45 minutes consult a veterinarian. For intravenous use only.

**ENTERING THE VEIN AND MAKING THE INJECTION**
1. Route the vein: this is accomplished by tying the choke rope tight 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 Figure 4.) 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 on the side of the neck. 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 the thick-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 push 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 skin. 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 needle has been entered. Third, once in the vein, the needle should be inserted along the length of the vein all the way to the heart, exercising caution to see that the needle does not penetrate to 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. Remove the rubber stopper from the bottle of intravenous solution, connect the intravenous tube to the neck of the bottle, invert the bottle and allow some of the solution to run through the tube to eliminate all air bubbles.

4. Making the injection. With needle in proper position as indicated by a continuous flow of blood, release the choke rope by a quick pull on the rope. This is essential - the medication cannot flow into the vein while the rope is taut. Immediately connect the intravenous tube to the needle, and raise the bottle. The solution will flow by gravity. (See Figure 5.) Rapid injection may occasionally produce shock. Administer slowly. The animal should be observed at all times during the injection in order not to give the solution too fast. This may be determined by watching the respiration of the animal and feeling or listening to the heart beat. If the heart beat and respiration increase markedly, the rate of injection should be immediately stopped by pinching the tube until the animal recovers approximately to its previous respiration or heart beat rate, when the injection can be resumed at a slower rate. The rate of flow can be controlled by pinching the tube between the thumb and forefinger or by raising or lowering the bottle.

![Figure 5](image)

**Bubbles entering the bottle through the air tube or valve indicate the rate at which the medication is flowing. If the flow should stop, this means that the needle has slipped out of the vein (or is clogged) and the operation will have to be repeated. In using the syringe technique, pull back gently on the plunger; if blood flows into the syringe, the needle is in proper position. Depress the plunger slowly. If there is any resistance to the depression of the plunger, stop and repeat insertion procedure. The resistance indicates that either the needle is clogged or it has slipped out of the vein. With either method of administration, syringe or gravity flow, 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. Sudden movement of the animal, especially twisting of the neck or raising or lowering the head, may sometimes cause the needle to slip out of the vein. To prevent this, tape the needle hub to the skin of the neck to hold the needle in position. Whenever there is any doubt as to the position of the needle, this should be checked in the following manner: Flesch off the intravenous tube to stop flow, disconnect the tube from the needle and re-apply pressure to the vein. Free flow of blood through the needle indicates that it is in proper position and the injection can then be continued. If using the syringe, gently pull back on the plunger. Blood should flow into the syringe.

5. Removing the needle. When the injection is complete, remove needle with a straight pull. Then apply pressure for a moment to control any bleeding through needle puncture, using cotton soaked in alcohol or other suitable antiseptic.

**INSTRUCTIONS FOR CARE OF SICK ANIMALS**
The use of antibiotics, as with most medications used in the management of diseases, is based on accurate diagnosis and adequate treatment. When properly used in the treatment of diseases caused by oxygenate the susceptible organisms, animals usually show a noticeable improvement within 24 to 48 hours. If improvement does not occur within this period of time, the diagnostic and treatment of animal diseases should be carried out by a veterinarian. The use of professional veterinary and laboratory services can reduce treatment costs, times and needless losses. Good management, housing, sanitation and nutrition are essential in the care of animals and in the successful treatment of disease.
OXYTET 10 INJECTION
Oxytetracycline Hydrochloride Injection

ANTIBIOTIC
100 mg/mL

FOR USE IN ANIMALS ONLY
RESTRICTING DRUG USE HUMAN USE ONLY AS DIRECTED
KEEP OUT OF REACH OF CHILDREN

NET CONTENTS: 100 mL

Norbrook

EACH mL CONTAINS:
Oxytetracycline HCL 100 mg
Magnesium Chloride 6 H2O 5.95% w/v
Water for Injection 17.6% w/v
Propylene Glycol 6.6%
Sodium Bisulfite 5.3% w/v
as a preservative and Monochloramine for pH adjustment.

NOTE: Solution may darken on storage but potency remains unaffected.

STORAGE TEMPERATURE:
Store at controlled room temperature 10°-30°C (50°-
86°F). Protect from freezing.
Made in UK

Manufactured for:
Norbrook, Inc.
Lenox, KS 66219
Lot No.
Exp Date.
Indications: Oxytet 10 Injection (Oxytetracycline Hydrochloride Injection) is for the treatment of bacterial pneumonia and shipping fever complex associated with Pasteurella spp., bacterial enteritis (coccid) caused by Zoonorochete coli, neosporosis caused by Neospora caninum, and certain strains of Clostridium perfringens and Actinobacillus suis. Wound injection and traumatic injury caused by oxytetracycline susceptible strains of streptococci, staphylococci, and clostridia. Damage and Administration: 5 mg/lb body weight per day for a maximum of 4 consecutive days, for intravenous administration only.

See package insert for complete directions and warnings.

WARNING: Discontinue treatment at least 21 days prior to slaughter. Not for use in lactating dairy cattle. A withdrawal period has not been established for this product for non-ruminant animals. Do not use in calves to be processed for veal. Rapid intravenous administration may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 3 minutes.

CAUTION: If no improvement occurs within 24 to 48 hours, consult a veterinarian.

Do not give the drug for more than 4 consecutive days. Use beyond 4 days or dosage higher than the maximum recommended dose may result in antibiotic residue in the tissues beyond the withdrawal time.

ANADA 200-452, Approved by FDA

EACH mL CONTAINS:
Oxytetracycline HCl 100 mg
Magnesium Chloride + 6 H2O 5.75% w/v
Water for Injection 17.0% w/v
Propylene Glycol q.s.
With Sodium Formaldehyde Sulfoxylate 1.3% w/v, as a preservative and Monoethanolamine for pH adjustment.

NOTE: Solution may darken on storage but potency remains unaffected.

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

Made in UK

Manufactured for:
Norbrook, Inc.
Lenexa, KS 66219

Lot No.: 
Exp. Date:
Indications: Oxytet 10 Injection (Oxytetracycline Hydrochloride) is indicated for the treatment of bacterial pneumonia and septicemia, fever complex associated with Pasteurella spp., bacterial encephalitis (sepsis) caused by Pasteurella spp., enteric colitis, cellulitis caused by Pasteurella multocida, wound infections, and traumatic injury caused by oxytetracycline susceptible strains of streptococci and staphylococci bacteria.

Dosage and Administration: 30 mg/kg body weight per day for a maximum of 4 consecutive days. For intravenous administration only.

See package insert for complete directions and warnings.

WARNING: Discontinue treatment at least 24 days prior to slaughter. NOT for use in lactating dairy cattle. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Rigid intravenous administration may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes.

CAUTION: If no improvement occurs within 24 to 48 hours, consult a veterinarian.

Do not use the drug for more than 4 consecutive days. Use beyond 4 days or dosage higher than the maximum recommended dose may result in antibiotic residue in the tissues beyond the withdrawal time.

Each mL contains:
- Oxytetracycline HCl 100 mg
- Magnesium Chloride 6 H2O 5.75% w/v
- Water for Injection 17.0% v/v
- Propylene Glycol 0.5%
- With Sodium Formaldehyde Sulfonate 1.3% w/v, as a preservative and Monothanolamine for pH adjustment.

NOTE: Solution may darken on storage but potency remains unaffected.

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

Made in UK

Manufactured for:
Norbrook, Inc.
Lenexa, KS 66219

Lot No.: Exp. Date:
Oxytet 10 Injection is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline.

Each mL contains: 100 mg of oxytetracycline hydrochloride.

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

CAUTION: If no improvement occurs within 24 to 48 hours, consult a veterinarian.

WARNING: Discontinue treatment at least 22 days prior to slaughter of the animal. Not for use in lactating dairy animals. A withdrawal period has not been established for this product in pre-ruminating calves. DO not use in calves intended for veal. Rapid Intravenous administration may result in animal collapse. Oxytetracycline should be administered slowly over a period of at least 5 minutes.

PRECAUTIONS: The improper or accidental injection of the drug outside of the vein will cause local tissue irritation manifested by temporary swelling and discoloration at the injection site.

Refer to Package Insert for Complete Directions and Warnings.


Note: Solution may darken on storage but potency remains unaffected.

Cattle Slaughter Guide: The following dosage of Oxytet 10 Injection is recommended for the treatment of disease in cattle as indicated in the following table:

<table>
<thead>
<tr>
<th>Cattle Weight (lbs)</th>
<th>Per 100 lbs</th>
<th>Number of 10 mL vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>0.3</td>
<td>1</td>
</tr>
<tr>
<td>100</td>
<td>0.6</td>
<td>2</td>
</tr>
<tr>
<td>200</td>
<td>1.2</td>
<td>4</td>
</tr>
<tr>
<td>300</td>
<td>1.8</td>
<td>6</td>
</tr>
<tr>
<td>400</td>
<td>2.4</td>
<td>8</td>
</tr>
<tr>
<td>500</td>
<td>3.0</td>
<td>10</td>
</tr>
<tr>
<td>600</td>
<td>3.6</td>
<td>12</td>
</tr>
<tr>
<td>700</td>
<td>4.2</td>
<td>14</td>
</tr>
<tr>
<td>800</td>
<td>4.8</td>
<td>16</td>
</tr>
<tr>
<td>900</td>
<td>5.4</td>
<td>18</td>
</tr>
<tr>
<td>1000</td>
<td>6.0</td>
<td>20</td>
</tr>
<tr>
<td>1100</td>
<td>6.6</td>
<td>22</td>
</tr>
<tr>
<td>1200</td>
<td>7.2</td>
<td>24</td>
</tr>
</tbody>
</table>

*See package insert for dosage instructions for other indicated diseases and full product information.
Oxytetracycline HCl Injection

ANTIBIOTIC

Each mL contains 100 mg Oxytetracycline HCl

For Use in Beef Cattle, Beef Calves, Non-lactating Dairy Cattle and Dairy Calves Only

DESCRIPTION

Oxytetracycline Hydrochloride Injection is a sterile ready-to-use preparation containing 100 mg/mL Oxytetracycline HCl for administration of the broad spectrum antibiotic, Oxytetracycline, by injection.

ANTIBIOTIC ACTION OF OXYTETRACYCLINE

Oxytetracycline is effective against a wide range of gram-negative and gram-positive organisms that are pathogenic for cattle. The antibiotic is primarily bacteriostatic in effect, and is believed to exert its antibacterial action by the inhibition of microbial protein synthesis. The antibiotic activity of Oxytetracycline is not appreciably diminished in the presence of body fluids, serum or edemas. Since the drugs in the tetracycline class have similar antibacterial spectra, organisms can develop cross resistance among them. Oxytetracycline is concentrated by the liver in bile and excreted in the urine and feces at high concentrations and in a biologically active form.

WARNING

Discontinue treatment with Oxytetracycline Hydrochloride injection at least 22 days prior to slaughter of the animal. Not for use in lactating dairy animals.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

CAUTION

Store at 59°-86°F. If no improvement occurs within 24 to 48 hours, consult a veterinarian. Do not use the drug for more than 4 consecutive days. Use beyond 4 days or doses higher than maximum recommended dose may result in antibiotic tissue residues beyond the withdrawal period.

PRECAUTIONS

The improper or accidental injection of the drug outside of the vein will cause local tissue irritation manifested by temporary swelling and discoloration at the injection site.

Shortly after injection, treated animals may have a transient hemorrhagic (darkened) urine.

Reactions of an allergic or hypersensitivity nature, sometimes fatal, have been known to occur in hypersensitive animals following the injection of Oxytetracycline solutions, but such reactions are rare.

As the first sign of any adverse reaction or anaphylactic shock (noted by glassy eyes, increased salivation, grinning of the teeth, rapid breathing, muscular tremors, staggering, swelling of the veins or collapse), the product should be discontinued. Epinephrine solution at the recommended dosage levels should be administered and a veterinarian should be called immediately.

Because bacteriostatic drugs interfere with the bactericidal action of Penicillin, do not give Oxytetracycline Hydrochloride in conjunction with Penicillin.

As with other antibiotics, use of this drug may result in over-growth of non-susceptible organisms. If any unusual symptoms occur or if the absence of a favorable response following treatment, discontinue use immediately and call a veterinarian.

GENERAL INDICATIONS FOR USE

A great many of the pathogens involved in cattle diseases are known to be susceptible to Oxytetracycline Hydrochloride therapy. Many strains of organisms, however, have shown resistance to Oxytetracycline. In the case of certain coliforms, streptococci and staphylococci, it may be advisable to conduct culture and sensitivity testing to determine susceptibility of the offending organism to Oxytetracycline. In this manner, the likelihood of successful treatment with Oxytetracycline Hydrochloride injection can be determined in advance.

DISEASES FOR WHICH OXYTETRACYCLINE HYDROCHLORIDE INJECTION IS INDICATED

The use of Oxytetracycline Hydrochloride Injection is indicated in beef cattle, beef calves, non-lactating dairy cattle and dairy calves for treatment of the following disease conditions caused by one or more of the Oxytetracycline sensitive pathogens listed as follows:

1. Bacterial infections of the skin and subcutaneous tissues.
2. Bacterial infections of the respiratory system, including pneumonia and bronchitis.
3. Bacterial infections of the urogenital system, including ascending urinary tract infections.
4. Bacterial infections of the digestive system, including enteritis and colitis.
5. Bacterial infections of the biliary tract, including cholangitis.
6. Bacterial infections of the blood and bone marrow.

NADA 108-963, Approved by FDA

Oxytetracycline Hydrochloride Injection is a sterile ready-to-use preparation containing 100 mg/mL Oxytetracycline HCl for administration of the broad spectrum antibiotic, Oxytetracycline, by injection.
**Disease**

- Bacterial Pneumonia and Shipping Fever Complex Associated with Pasteurella spp.
- Bacterial Encephalitis (Sovereign Lobe)
- Leptospirosis (Filamental Foot Rot)
- Cat Diphtheria
- Wounds Tongue
- Wound Infections: Acute Metritis
- Traumatic Injury

**Caustive Organism(s): Which Show Sensitivity to Oxytetracycline HCl Injection**

- Pasteurella spp
- E. coli
- Clostridium perfringens
- Streptococcal organisms
- Anaerobes

**RECOMMENDED DAILY DOSAGES**

- Use at first clinical signs of disease.
- The recommended dosage of 5 to 15 mg of Oxytetracycline Hydrochloride per pound of body weight is recommended for use in acute cases.
- Use a 10% solution of the drug to be used in acute cases.

**Directions for Making an Intravenous Injection in Cattle**

1. **Equipment Recommended**
   - Cattle rope — a rope or cord about 5 feet long, with a loop in one end, to be used as a noose.
   - Syringe and needle: gravity flow intravenous set. (See Fig. 1.)

2. **PREPARATION OF EQUIPMENT**
   - Thoroughly clean the needle, syringe and intravenous set and discard them by boiling in water for 30 minutes or by immersing in a suitable chemical disinfectant such as 70% alcohol for a period of not less than 10 minutes. Warm the bottle of medication to approximately body temperature and keep warm until used.
   - It is recommended that the correct dose be diluted in water for injection, sodium chloride injection or other suitable vehicle immediately prior to administration. Doses up to 50 ml may be diluted in 250 ml. Larger doses may be diluted in 500 ml of one of the diluents. Adverse reactions may be minimized and the drug dose can be better regulated by this method of dilution.
   - Avoid touching the needle with the hands at all times.
   - In the case of the syringe method of administration, distill the solution by using 70% alcohol or other suitable disinfectant. Touching a sterile needle only by the hub, attach it to the syringe and push the plunger down the barrel to empty 5 ml. Pierce the rubber stopper of the solution and withdraw the plunger upward in the syringe to draw up a volume of Oxytetracycline HCl equal to 100 mg, of about 6 ml. More than is needed for injection. Withdraw from the vein and弄得 the needle upward, remove all air bubbles from the syringe by pushing the plunger upward to the volume required.
   - If the injection cannot be made immediately, the tip of the needle may be covered with cotton soaked in 70% alcohol to prevent contamination.

3. **PREPARATION OF THE ANIMAL FOR INJECTION**
   - Approximate location of veins. The jugular vein runs in the jugular groove on each side of the neck from the angle of the jaw to just above the scrotum and slightly above and to the side of the spine. (See Figure 2 and 3.)

4. **ENTERING THE VEIN AND MAKING THE INJECTION**
   - Place the vein in the left hand, the needle in the right hand. Hold the needle with the point at the level of the vein and to the left of the vein. Begin to fill the needle with a small amount of solution. The needle should be inserted at a 45-degree angle to the skin and should not penetrate too deeply into the skin. When the needle is in place, a small amount of solution is used to fill the needle. The needle should be advanced slowly, and the solution should be allowed to flow slowly and steadily. The needle should be removed from the vein (or drogled) and another attempt must be made. If difficulty is encountered, try to remove the needle. An assistant should be available to use the vein on the other side of the neck.

5. **CAUTION:** No improvement is noted within 24 to 48 hours consult a veterinarian.

**DOSAGE FOR INJECTION**

Refer to the table below for proper dosage according to body weight of the animal.

<table>
<thead>
<tr>
<th>Weight of Animal (lbs)</th>
<th>Daily Dosage of Oxytetracycline Hydrochloride (mg)</th>
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<tbody>
<tr>
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**CAUTION:** If no improvement is noted within 24 to 48 hours consult a veterinarian.
MEDAMYCIN®-100
OXYTETRACYCLINE
HYDROCHLORIDE INJECTION
ANTIBIOTIC
100 mg/mL
Sterile
FOR USE IN ANIMALS ONLY
RESTRICTED DRUG (CALIFORNIA)
USE ONLY AS DIRECTED
KEEP OUT OF REACH OF CHILDREN
NADA 106-963, Approved by FDA

NET CONTENTS:
500 mL

INDICATIONS: MEDAMYCIN Oxytetracycline Hydrochloride Injection is for the treatment of diseases in beef cattle, beef calves, nonlactating dairy cattle and dairy calves caused by pathogens sensitive to Oxytetracycline HCl.

Dosage and Administration: 5 mg/kg body weight per day for a maximum of 4 consecutive days. For intravenous administration only.

See package insert for complete directions and warnings.

WARNING: Discontinue treatment at least 22 days prior to slaughter. NOT for use in lactating dairy cattle. A withdrawal period has not been established for this product in pre-weaned calves. Do not use in calves to be processed for veal.

CAUTION: If no improvement occurs within 24 to 48 hours, consult a veterinarian.

Do not use the drug for more than 4 consecutive days. Use beyond 4 days or dosage higher than the maximum recommended dose may result in antibiotic residue in the tissues beyond the withdrawal time.

Lot No.: Exp. Date:

Each mL contains:
Oxytetracycline HCl…………………………………100 mg
Magnesium Chloride 4H2O…1.75% w/v
Water for Injection…………………………………17.0% w/v
Propylene Glycol………………………………..…0.4%
With Sodium Benzoate and Sodium Sulfate, 1.5% w/v, as a preservative and Miconazole Nitrate for pH adjustment. NOG: Solution may darken on storage but potency remains unaffected.
Storage Temperature: 25°-81°F

TechAmerica™

Made By:
Fenwicks Animal Health Co.
Kansas City, MO 64153

Toll Free: 1-800-267-8800

DIL-26589209