



Product Safety Data Sheet
Oxytet 20% for US

1. IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY / UNDERTAKING

Product Name Oxytet 20% for US
 Manufacturer Norbrook Laboratories Ltd,
 Station Works, Newry, Co.Down,
 N.Ireland, BT35 6JP.
 Supplier Norbrook, Inc.
 3517 Enterprise DR, Suite D
 Kansas City, MO 64129
 Phone: 816 861 0189
 Fax: 816 861 2691
 Enquiries : jbnorbrook@aol.com

2. COMPOSITION / INFORMATION ON INGREDIENTS

<i>Substance/Preparation</i>	<i>Active Ingredients</i>	<i>Description</i>	<i>Chemical Family</i>
Preparation	Oxytetracycline Base	Antibacterial	Tetracyclines

3. HAZARDS IDENTIFICATION

Physical and Chemical Hazards : Not classified as dangerous under EEC Directives 67/548/EEC, 88/379/EEC or 99/45/EC.
 Environmental Hazards : None known
 Adverse Human Health Effects : There are no known adverse effects of exposure to Oxytet 20% for US.

4. FIRST AID MEASURES

Inhalation : Remove to fresh air. If any signs or symptoms occur or persist seek medical advice.
 Skin Contact : Wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse.
 Eyes Contact : Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.
 Ingestion : Wash out mouth thoroughly with water and give plenty of water to drink. Do not induce vomiting. Seek medical attention.



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5. FIRE FIGHTING MEASURES

Extinguishing media: Use carbon dioxide, dry chemical or alcohol-resistant foam spray extinguishers. Use water spray to cool fire-exposed containers. A fine water mist may be used to smother or to disperse vapours.

Fire and explosion hazards: None.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : Provide good ventilation. Prevent skin and eye contact.

Environmental Precautions: Keep away from drains, surface-water, ground-water and soil.

Method for Clean-up : Absorb small spills on spill pillows, sand, sawdust or other suitable absorbing material.

7. HANDLING AND STORAGE

Handling : Avoid contact with eyes, skin or clothing. Do not breathe vapours or mist. Do not ingest. Do not smoke or eat while handling the product. Wash thoroughly after handling. The containers should be stored in their original boxes when not in use.

Storage : Store in closed containers in a cool, dry, well-ventilated area, between 15°C and 30°C and away from oxidisers, heat, sparks and open flame. Protect containers from physical damage and light. Keep from freezing.

Keep container closed when not in use. Do not transfer contents to unlabelled containers. Use only with adequate ventilation. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Component - Occupational Exposure Standard

Oxytetracycline Hydrochloride

Not Established

For pure oxytetracycline :

LD50 (Oral, mouse) 2240 mg/kg

LD50 (Oral, rat) 4800 mg/kg

Protective Equipment : Wear vinyl, nitrile or rubber gloves, a waterproof bib-apron and suitable eye protection when applying the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form : Sterile aqueous solution



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Colour : Clear, yellow/brown
Odour : None.

10. STABILITY AND REACTIVITY

Stability : Stable under normal temperatures and pressures.
Conditions to avoid : None known
Materials to avoid : None known

11. TOXICOLOGICAL INFORMATION

Exposure Effects (Acute)

Eye Contact : Direct contact of the solution with eyes can cause irritation.
Skin Contact : Prolonged or repeated contact with Oxytet 20% for US may cause irritation and/or drying and cracking of the skin.
Inhalation : None known.
Ingestion : Oral toxicity of the Oxytet 20% for US solution is low.

Exposure Effects (Chronic)

Unknown for the product mixture. When this product is used according to the directions, prolonged exposure of man is not expected. Both its mutagenicity and its teratogenicity are not known.

12. ECOLOGICAL INFORMATION

Data on the ecological implications for Oxytet 20% for US is not yet available.

13. DISPOSAL CONSIDERATIONS

Product/Residues : Do not discharge the product material into surface or waste water. For disposal, use an incinerator licensed for chemical waste.
Package : Dispose of waste containers using regular disposal methods in accordance with local and national environmental regulations.

14. TRANSPORT INFORMATION

Land Transport

ADR No., RID No., UN No. : Not applicable

Sea Transport



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IMO / IMDG code, UN No. : Not applicable

Air Transport

IATA / ICAO Class, Un No. : Not applicable

15. REGULATORY INFORMATION

Labelling Information : None

Safety phrases : S2 Keep out of reach of children
S7 Keep container tightly closed

16. OTHER INFORMATION

For Animal Treatment Only

Injectable solution 200mg/ml

ANADA 200-306, approved by FDA

Updated PSDS Creation Date : 10/12/02

Suppliers data sheets and various chemicals and pharmaceuticals databases were used to compile this sheet.

The information contained in this PSDS is believed to be accurate and represents the best information available at the time of preparation. However Norbrook Laboratories Limited makes no warranty, express or implied, with respect to such information and assumes no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes, and Norbrook Laboratories Limited will not be held liable for any damage resulting from the handling of or contact with the above product.

OXYTET 200 (200 mg/mL)

(oxytetracycline injection)
ANADA 200-306, approved by FDA

ANTIBIOTIC

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

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

For animal use only.

Read Entire Package Insert Carefully Before Using This Product.

Oxytet 200 (200 mg/mL) (oxytetracycline injection) is a sterile, ready-to-use solution for the administration of the broad-spectrum antibiotic oxytetracycline by injection.

Oxytet 200 (200 mg/mL) 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.

WARNING:

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.

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 Oxytet 200 (200 mg/mL) be administered slowly by this route.

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

As with all antibiotic preparations, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. A lack of response by the treated animals, 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 Oxytet 200 (200 mg/mL) 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 Oxytet 200 (200 mg/mL) 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:

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

Cattle: Oxytet 200 (200 mg/mL) is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., and *Hamophilus* 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 acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

Swine: Oxytet 200 (200 mg/mL) 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, Oxytet 200 (200 mg/mL) is indicated as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

DOSEAGE:

Cattle: Oxytet 200 (200 mg/mL) is to be administered by intramuscular, subcutaneous, or intravenous injection to beef cattle; dairy cattle; and calves, including preruminating (veal) calves.

A single dosage of 9 mg of Oxytet 200 (200 mg/mL) 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 repeated restraint is inadvisable.
- (2) infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella* bovis.

Oxytet 200 (200 mg/mL) 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: In swine a single dosage of 9 mg of Oxytet 200 (200 mg/mL) per lb 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.

Oxytet 200 (200 mg/mL) 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, Oxytet 200 (200 mg/mL) 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 Oxytet 200 (200 mg/mL)		3 or 5 mg/lb Dosage Volume of Undiluted Oxytet 200 (200 mg/mL)	
	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 of Oxytet 200 (200 mg/mL) 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:

Oxytet 200 (200 mg/mL) 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, Oxytet 200 (200 mg/mL) 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 of 2-3 inches in length 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:

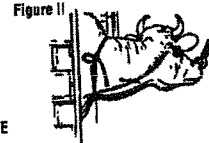
Oxytet 200 (200 mg/mL) may be administered intravenously to beef and dairy cattle. As with all highly concentrated materials, Oxytet 200 (200 mg/mL) should be administered slowly by the intravenous route.

Preparation of the Animal for Injection:

1. Approximate the location of vein. The jugular vein runs in the jugular groove on each side of the neck from the angle of the jaw to just above the brisket and slightly above and to the side of the windpipe (see Fig. 1).

2. Restraint. A stanchion or chute is ideal for restraining the animal. With a halter, rope, or cattle leader (nose tongs), pull the animal's head around the side of the stanchion, cattle chute, or post in such a manner to form a bow in the neck (see Fig. 1), 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. 1). 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 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 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 Oxytet 200 (200 mg/mL) (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 area of injection momentarily to control any bleeding through needle puncture, using cotton soaked in alcohol or other suitable antiseptic.

Not for Human Use. Restricted Drug. Use Only as Directed.

MANUFACTURED FOR:

Norbrook, Inc.
Lenexa, KS 66219

MADE IN THE UK



007670101

NORBROOK PRINTROOM Artwork Specification - from Stephen Teer - 3/12/07

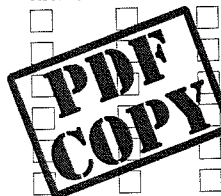
Norbrook
Pharmaceuticals Worldwide

Customer..... Norbrook
Country..... USA
Product..... Oxytet 200
Resource Code..... 6405007670
Revision Level..... 101
Pharma Code..... None
Insert Size..... Double Sided A5
Dimensions..... 148 x 210mm

COLOURS USED:

■ PMS Black

TINT OF COLOUR USED:



Tel. Ext. - 3291

email:
stephen.teer@norbrook.co.uk

APPROVED ARTWORK SENT TO PRINT BY:

Designer : Stephen Teer

Date : 3/12/07

Artwork Specification for CARTONCARE - from Stephen Teer - 3/12/07



Customer..... Norbrook
 Country..... USA
 Product..... Oxytet 200
 Volume..... 500ml
 Resource Code..... 6215077
 Revision Level..... C01
 Pharma Code..... None
 Barcode..... 5029534006626
 Dimensions..... 79 x 79 x 184mm
 Keyline (Die) Ref..... KLD0126

COLOURS USED:	TINT OF COLOUR USED:
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Artwork Department
 Station Works, Newry, Co. Down, BT35 6LP
 Tel: +44 (0) 28 3029 4235
 Fax: +44 (0) 28 3026 6499
 Email: +44 (0) 28 3026 8308
 e-mail: stephen.teer@norbrook.co.uk
 APPROVED ARTWORK SENT TO PRINT BY:
 Designer: Stephen Teer
 Date: 3/12/07

THIS FLAP
 VARNISH
 FREE

6215077C01

Oxytet 200 (200 mg/mL) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline.

CAUTION:

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

WARNING:

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 cattle and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Refer to Package Insert for Complete Directions

Storage:

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

Restricted Drug(s) (California),

Not for Human Use

Use Only as Directed.

Manufactured for:
 Norbrook, Inc.
 Lenexa, KS 66219

Made in the U.K.

Oxytet 200 (200 mg/mL)
 [oxytetracycline Injection]
 ANADA 200-306, approved by FDA

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

TAKE TIME



OBSERVE LABEL DIRECTIONS

Oxytet 200
 (200 mg/mL)
 [Oxytetracycline Injection]
 ANADA 200-306,
 approved by FDA

500 mL



CATTLE DOSAGE GUIDE

At the first signs of pneumonia or pinkeye,* administer a single dose of Oxytet 200 (200 mg/mL) by deep intramuscular injection, or subcutaneously, according to the following weight categories.**

Animal Weight (lb)	Number of mL or cc
100	4.5
200	9.0
300	13.5
400	18.0
500	22.5
600	27.0
700	31.5
800	36.0
900	40.5
1000	45.0
1100	49.5
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 Oxytet 200 (200 mg/mL) by deep intramuscular injection, according to the following weight categories.**

Animal Weight (lb)	Number of mL or cc
10	0.5
15	1.1
25	2.3
50	4.5
75	6.8
100	9.0
125	11.3
150	13.5
175	15.8
200	18.0
225	20.3
250	22.5
275	24.8
300	27.0
325	29.3

* 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.



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