Date of Approval: May 30, 2019

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-537

OxyMed™ LA

oxytetracycline injection

Swine, beef cattle, dairy cattle, and calves including preruminating (veal) calves

Cattle: OxyMed™ LA is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* 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: OxyMed™ LA 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, OxyMed™ LA is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

Sponsored by:

Bimeda Animal Health Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-537

B. Sponsor

Bimeda Animal Health Ltd.,
1B The Herbert Building,
The Park, Carrickmines,
Dublin, 18, Ireland

Drug Labeler Code: 061133

US Agent Name and Address:
Bimeda Inc.
291 Forest Prairie Road
Le Sueur, MN 56058-4520

C. Proprietary Name

OxyMed™ LA

D. Drug Product Established Name

oxytetracycline injection

E. Pharmacological Category

Antibiotic

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

200 mg/mL of oxytetracycline base as oxytetracycline dihydrate

H. How Supplied

250 mL and 500 mL multi-dose amber vials

I. Dispensing Status

OTC

J. Dosage Regimen

Cattle:

OxyMed™ LA 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 OxyMed™ LA 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*. OxyMed™ LA 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 beginning of treatment.

CATTLE DOSAGE GUIDE

At the first signs of pneumonia or pinkeye, administer a single dose of OxyMed™ LA subcutaneously, according to the following weight categories.[1]

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

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

Swine:

A single dosage of 9 mg of OxyMed™ LA 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. OxyMed™ LA 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 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, OxyMed™ LA should be administered undiluted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 or 5 mg/lb.

9 mg/lb Dosage

Body Weight	Volume of Undiluted OxyMed™ LA 9 mg/lb
5 lb	0.2 mL
10 lb	0.5 mL
25 lb	1.1 mL

3 or 5 mg/lb Dosage

Body Weight	Volume of Diluted OxyMed™ LA 3 mg/lb	Dilution*	Volume of Diluted OxyMed™ LA 5 mg/lb
5 lb	0.6 mL	1:7	1.0 mL
10 lb	0.9 mL	1:5	1.5 mL
25 lb	1.5 mL	1:3	2.5 mL

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

SWINE DOSAGE GUIDE

At the first signs of pneumonia, administer OxyMed™ LA by deep intramuscular injection according to the following weight categories.[1]

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

[1]Do not administer more than 5 mL at any one injection site.

K. Route of Administration

Subcutaneous, intramuscular, or intravenous injection

L. Species/Class

Swine, beef cattle, dairy cattle, and calves including preruminating (veal) calves

M. Indications

OxyMed™ LA 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:
OxyMed™ LA is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* 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:
OxyMed™ LA 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, OxyMed™ LA is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

N. Reference Listed New Animal Drug

Liquamycin® LA-200®; oxytetracycline injection; NADA 113-232; Zoetis Inc.

II. BIOEQUIVALENCE

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 (reference listed new animal drug (RLNAD)). 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 RLNAD, 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 period for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Bimeda Animal Health Ltd., was granted a biowaiver for the generic product OxyMed™ LA (oxytetracycline injection). The generic drug product is an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is Liquamycin® LA-200® (oxytetracycline injection), sponsored by Zoetis Inc., under NADA 113-232 and, was approved for use in cattle and swine on March 14, 1980.

III. EFFECTIVENESS

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY

The following are assigned to this product for cattle and swine:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of tetracycline (chlortetracycline, oxytetracycline, and tetracycline) is 25 micrograms *per* kilogram of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 2 parts *per* million (ppm) is established for the sum of tetracycline residues in muscle, 6 ppm in liver, 12 ppm in fat and kidney, and 0.3 ppm in milk, under 21 CFR 556.500.

B. Withdrawal Periods

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 28 days has been established for oxytetracycline in cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of oxytetracycline is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical method, please submit a Freedom of Information Summary request to: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

VI. USER SAFETY

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans, handling, administering, or exposed to OxyMed™ LA:

NOT FOR HUMAN USE
KEEP OUT OF REACH OF CHILDREN

VII. AGENCY CONCLUSIONS

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that OxyMed™ LA, when used according to the label, is safe and effective.

Additionally, data demonstrate that residues in food products derived from species treated with OxyMed™ LA will not represent a public health concern when the product is used according to the label.