Date of Approval: April 19, 2013

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-538

CLINDAMED Oral Drops

clindamycin

liquid

Cats and Dogs

This approval (for use in dogs and cats) is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

Dogs:
Skin infections (wounds and abscesses) due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*). Deep wounds and abscesses due to *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.
Dental infections due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.
Osteomyelitis due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

Cats:
Skin infections (wounds and abscesses) due to *Staphylococcus aureus*, *Staphylococcus intermedius, Streptococcus* spp. Deep wounds and abscesses due to *Clostridium perfringens* and *Bacteroides fragilis*.
Dental infections due to *Staphylococcus aureus, Staphylococcus intermedius, Streptococcus* spp., *Clostridium perfringens* and *Bacteroides fragilis*.

Sponsored by:

Cross Vetpharm Group Ltd.

Table of Contents

I. GENERAL INFORMATION:

A. File Number

ANADA 200-538

B. Sponsor

Cross Vetpharm Group Ltd.
Broomhill Rd.
Tallaght, Dublin 24, Ireland

Drug Labeler Code: 061623

U.S. Agent:
Ms. Linda M. Duple
Bimeda, Inc.
2836 Dolliver Park Avenue
Lehigh, IA 50557

C. Proprietary Name

CLINDAMED Oral Drops

D. Established Name

clindamycin

E. Pharmacological Category

Antimicrobial

F. Dosage Form:

Liquid

G. Amount of Active Ingredient

Each mL contains clindamycin hydrochloride equivalent to 25 mg clindamycin

H. How Supplied

20 mL filled in 30 mL bottles (25 mg/mL) supplied in packers containing 12 cartoned bottles with direction labels and calibrated dosing droppers

I. Dispensing Status

Rx

J. Dosage Regimen

Dogs: Infected Wounds, Abscesses, and Dental Infections
Oral: 2.5-15.0 mg/lb body weight every 12 hours.
Duration: Treatment may be continued up to a maximum of 28 days if clinical judgment indicates. Treatment of acute infections should not be continued for more than three or four days if no response to therapy is seen.

Dosage Schedule: Administer 1-6 mL/10 lbs body weight every 12 hours.

Dogs: Osteomyelitis
Oral: 5.0-15.0 mg/lb body weight every 12 hours.
Duration: Treatment is recommended for a minimum of 28 days. Treatment should not be continued for longer than 28 days if no response to therapy is seen.
Dosage Schedule: Administer 2-6 mL/10 lbs body weight every 12 hours.

Cats: Infected Wounds, Abscesses, and Dental Infections
Oral: 5.0-15.0 mg/lb body weight once every 24 hours depending on the severity of the condition.
Duration: Treatment may be continued up to a maximum of 14 days if clinical judgment indicates. Treatment of acute infections should not be continued for more than three to four days if no clinical response to therapy is seen.
Dosage Schedule: To provide 5.0 mg/lb, administer 1 mL/5 lbs body weight once every 24 hours; to provide 15.0 mg/lb, administer 3 mL/5 lbs body weight once every 24 hours.

K. Route of Administration

Oral

L. Species/Class

Dogs and cats

M. Indications

CLINDAMED Oral Drops (for use in dogs and cats) are indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

Dogs: Skin infections (wounds and abscesses) due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*). Deep wounds and abscesses due to *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.
Dental infections due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.
Osteomyelitis due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

Cats: Skin infections (wounds and abscesses) due to *Staphylococcus aureus*, *Staphylococcus intermedius, Streptococcus* spp. Deep wounds and abscesses due to *Clostridium perfringens* and *Bacteroides fragilis*.
Dental infections due to *Staphylococcus aureus, Staphylococcus intermedius, Streptococcus* spp., *Clostridium perfringens* and *Bacteroides fragilis*.

N. Reference Listed New Animal Drug

ANTIROBE AQUADROPS; (clindamycin); NADA 135-940; 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 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). 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 reference listed new animal drug (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 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, Cross Vetpharm Group Ltd. was granted a waiver from the requirement to demonstrate *in vivo* bioequivalence study for the generic product CLINDAMED (clindamycin) Oral Drops. The generic product is administered as an oral 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 absorption of the active ingredient. The RLNAD ANTIROBE AQUADROPS (clindamycin) liquid was approved under NADA 135-940 for use in dogs on November 17, 1989, and for use in cats on October 7, 1996.

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:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in dogs and cats, which are not food producing animals.

VI. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposure to CLINDAMED Oral Drops:

- Keep out of reach of children. Not for use in humans.

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 CLINDAMED Oral Drops, when used according to the label, is safe and effective.