

JUN - 6 2002

HFA 305

Clindamycin hydrochloride tablets

CLINTABS®

FREEDOM OF INFORMATION SUMMARY

ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-316

CLINTABS® (Clindamycin hydrochloride) 25 mg, 75 mg, and 150 mg tablets

For treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible gram positive and gram negative bacteria.

Sponsored by:

Delmarva Laboratories, Inc.

200-316-F015 /

FREEDOM OF INFORMATION SUMMARY - CLINTABS®

1. General Information

ANADA Number: 200-316

Sponsor: Delmarva Laboratories, Incorporated
1500 Huguenot Road
Suite 106
Midlothian, VA 23113
Labeler Code: 059079

Generic Name: Clindamycin hydrochloride 25 mg, 75 mg, and 150 mg tablets

Trade Name: Clintabs®

Dosage form: 25 mg, 75 mg, and 150 mg tablets.

How Supplied: 25 mg tablets supplied in bottles of 600.
75 mg tablets supplied in bottles of 200
150 mg tablets in bottles of 100.

How Dispensed: Rx

Amount of Active Ingredients: Each tablet contains clindamycin hydrochloride equivalent to 25mg, 75 mg, or 150 mg clindamycin, respectively.

Route of Administration: Oral

Species: Canine

Recommended Dosage: For therapy of wounds, abscesses, and dental infections, orally administer 2.5 mg/lb body weight every 12 hours for a 28 day maximum. For therapy of osteomyelitis, orally administer 5.0 mg/lb body weight every 12 hours for a 28 day minimum.

Pharmacological Category: Antibiotic

Indications for Use:

Dogs: Aerobic bacteria: Clintabs® (clindamycin hydrochloride) tablets are indicated for the treatment of soft tissue infections (wounds and abscesses), dental infections and osteomyelitis caused by susceptible strains of *Staphylococcus aureus*.

Anaerobic bacteria: Clintabs® (clindamycin hydrochloride) tablets are

indicated for the treatment of soft tissue infections (deep wounds and abscesses), dental infections and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis*, *Bacteroides melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

Pioneer Product: Antirobe® Capsules, clindamycin hydrochloride, NADA 120-161, Pharmacia and Upjohn.

2. Target Animal Safety and Effectiveness

This drug is the subject of the Generic Animal Drug and Patent Term Restoration Act of 1988 and is submitted as an Abbreviated New Animal Drug Application (ANADA). A Suitability Petition (SP 98P-0580/CP) dated July 16, 1998, was submitted by the Sponsor requesting approval for a generic tablet form of clindamycin hydrochloride which was subject of the pioneer drug, Antirobe® Capsules, NADA # 120-161, Pharmacia & Upjohn, the only approved solid oral dosage form. The Suitability Petition was approved by the Center for Veterinary Medicine, Food and Drug Administration on October 30, 1998.

A bioequivalence study comparing the bioavailability of the test article, Clintabs® (clindamycin hydrochloride) 150 mg tablets, to that of the reference article, Antirobe® (clindamycin hydrochloride) 150 mg Capsules, was conducted in dogs at Covance Laboratories, Vienna, Virginia. The investigation was conducted as a two periods, two sequences, and two-treatment crossover design employing twenty-four purebred Beagle dogs (12 males, 12 females). All animals were fasted from 12 hours prior to until 4 hours subsequent to dosing. On treatment Day 1, 12 dogs (6 males, 6 females) were orally administered one 150 mg Clintabs® tablet and 12 dogs (6 males, 6 females) were orally administered one 150 mg Antirobe® Capsule. On treatment day 15 the 2 groups of 12 dogs were orally administered the opposite drug from treatment Day 1. After drug administration, Days 1 and 15, blood was taken from each dog prior to dosing (0 hour) and at 0.5, 0.75, 1.0, 1.25, 1.5, 2.0, 4.0, 8.0, 12.0, 18.0, 24.0, 26.0, 36.0 and 48.0 hours relative to dosing. The serum was harvested, stored frozen, and subsequently analyzed for clindamycin concentration using a validated HPLC procedure.

The results of the in-vivo bioequivalence trial were as follows (Table 1):

Table 1: Pivotal bioavailability metrics, Clintabs vs Antirobe in dogs

Parameter	Antirobe geom mean	Clintabs geom mean	Clin/Anti	Diff LS means	SE diff	Lower CI	Upper CI
AUC _{0-LOQ} (µg*hr/mL)	22.77	24.32	1.07	0.0659	0.0556	0.97	1.17
C _{MAX} (µg*mL)	5.5	5.5	1.0	0.00273	0.03238	0.95	1.06

3. Human Safety: Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this ANADA. The drug is to be labeled for use in dogs only, which are non-food animals.

Human Safety Considerations Other than Food Safety:

The labeling includes the following statement: "WARNING -- Not for human use.

4. Agency Conclusions:

The data submitted in support of this original Abbreviated New Animal Drug Application (ANADA) filed under section 512 (b) satisfies the requirements of section 512 (n) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 514 of the implementing regulations. The data demonstrates that Clintabs® (clindamycin hydrochloride) is safe and effective when used under labeled conditions.

The innovator product, Antirobe® requires a Veterinarians prescription.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is judged to be critical in the diagnosis of bacterial infections in animals, treatment of these conditions, and monitoring for possible adverse effects of the drug.

Based upon the results of the in-vivo bioequivalence study, it is concluded that Delmarva's Clintabs® (150 mg clindamycin tablets) are bioequivalent to Antirobe® 150 mg clindamycin capsules. When used under its proposed conditions of use, it is safe and effective for its labeled indications.

5. Attachments: Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below.

Pioneer: (25 mg capsule, 75 mg capsule, 150 mg capsule, and package insert.)

Generic: (25 mg tablet, 75 mg tablet, 150 mg tablet, and package insert.)

120-161
7-14-99
15 300
59-86 F
→

Approved for use in canines.
Recommended dosage:
For therapy of wounds, abscesses and dental infections, 1 capsule for each 10 pounds body weight every 12 hours
For therapy of osteomyelitis, 1 capsule for each 5 pounds body weight every 12 hours
See package insert for complete product information
Warning - Not for human use
Keep container tightly closed
Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP]
Each capsule contains Clindamycin hydrochloride equivalent to clindamycin, 25 mg
812 771 106
5719-37/1

NDC 0009-3043-01
600 Capsules

Antirobe®
Capsules
clindamycin hydrochloride
25 mg

Equiv to 25 mg clindamycin

For Use in Animals Only

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

NADA #120-161, Approved by FDA



N 0009-3043-01 5



USP
definition
Label changes - 17/1/2000
Under
135-9410 # 025

Approved for use in canines.
Recommended dosage:
For therapy of wounds, abscesses and dental infections, 1 capsule for each 30 pounds body weight every 12 hours.
For therapy of osteomyelitis 1 capsule for each 15 pounds body weight every 12 hours
See package insert for complete product information.
Warning - Not for human use
Keep container tightly closed
Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].
Each capsule contains Clindamycin hydrochloride equivalent to clindamycin, 75 mg
812 765 104
5719-38/1

NDC 0009-3044-01
200 Capsules

Antirobe®
Capsules
clindamycin hydrochloride

75 mg

Equiv to 75 mg clindamycin

For Use in Animals Only

Caution: Federal (USA) law restricts the drug to use by or on the order of a licensed veterinarian

NADA #120-161, Approved by FDA



N 0009-3044-01 2

Open Here ▲



Approved for use in canines
Recommended dosage
For therapy of wounds, abscesses and dental infections, 1 capsule for each 80 pounds body weight every 12 hours
For therapy of osteomyelitis, 1 capsule for each 30 pounds body weight every 12 hours.
See package insert for complete product information.
Warning - Not for human use
Keep container tightly closed
Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].
Each capsule contains Clindamycin hydrochloride equivalent to clindamycin, 150 mg.
812 774 104
5719-39/1

NDC 0009-3045-01
100 Capsules

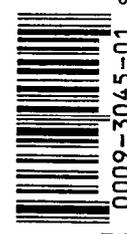
Antirobe®
Capsules
clindamycin hydrochloride
150 mg

Equiv to 150 mg clindamycin

For Use in Animals Only

Caution: Federal (USA) law restricts the drug to use by or on the order of a licensed veterinarian

NADA #120-161, Approved by FDA



N 0009-3045-01 9

Open Here ▲



Approved for use in canines
Recommended dosage
For therapy of wounds,
abscesses and dental infections,
1 tablet for each 10 pounds
body weight every 12 hours
For therapy of osteomyelitis,
1 tablet for each 5 pounds
body weight every 12 hours
See package insert for complete
product information.
Warning - Not for human use
Keep container tightly closed
Store at controlled room
temperature 20°-25° C
(68°-77° F)
Each tablet contains
Clindamycin hydrochloride
equivalent to clindamycin, 25 mg

Mfd for DELMARVA LABORATORIES, INC.
Midlothian, VA 23113
By DIAMOND ANIMAL HEALTH, INC.
Des Moines, IA 50327

NDC 59079-400-14
600 Tablets

CLINTABS®

Tablets
clindamycin hydrochloride

25 mg

Equiv to 25 mg clindamycin

For Use in Animals Only

Caution: Federal (USA) law restricts this drug to
use by or on the order of a licensed veterinarian

ANADA # 200-316 Approved by FDA



01849

Approved for use in canines
Recommended dosage
For therapy of wounds,
abscesses and dental infections,
1 tablet for each 10 pounds
body weight every 12 hours
For therapy of osteomyelitis,
1 tablet for each 5 pounds
body weight every 12 hours
See package insert for complete
product information.
Warning - Not for human use
Keep container tightly closed
Store at controlled room
temperature 20°-25° C
(68°-77° F)
Each tablet contains
Clindamycin hydrochloride
equivalent to clindamycin, 25 mg

Mfd for DELMARVA LABORATORIES, INC.
Midlothian, VA 23113
By DIAMOND ANIMAL HEALTH, INC.
Des Moines, IA 50327

NDC 59079 400 14
600 Tablets

CLINTABS®

Tablets
clindamycin hydrochloride

25 mg

Equiv to 25 mg clindamycin

For Use in Animals Only

Caution: Federal (USA) law restricts this drug to
use by or on the order of a licensed veterinarian

ANADA # 200-316 Approved by FDA



01849

Approved for use in canines
Recommended dosage
For therapy of wounds,
abscesses and dental infections,
1 tablet for each 10 pounds
body weight every 12 hours
For therapy of osteomyelitis,
1 tablet for each 5 pounds
body weight every 12 hours
See package insert for complete
product information.
Warning - Not for human use
Keep container tightly closed
Store at controlled room
temperature 20°-25° C
(68°-77° F)
Each tablet contains
Clindamycin hydrochloride
equivalent to clindamycin, 25 mg

Mfd for DELMARVA LABORATORIES, INC.
Midlothian, VA 23113
By DIAMOND ANIMAL HEALTH, INC.
Des Moines, IA 50327

NDC 59079-400-14
600 Tablets

CLINTABS®

Tablets
clindamycin hydrochloride

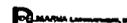
25 mg

Equiv to 25 mg clindamycin

For Use in Animals Only

Caution: Federal (USA) law restricts this drug to
use by or on the order of a licensed veterinarian

ANADA # 200-316 Approved by FDA



01849

Approved for use in canines
Recommended dosage:
For therapy of wounds,
abscesses and dental infections,
1 tablet for each 30 pounds
body weight every 12 hours.

For therapy of osteomyelitis,
1 tablet for each 15 pounds
body weight every 12 hours.

See package insert for complete
product information.

Warning - Not for human use
Keep container tightly closed

Store at controlled room
temperature 20°-25° C
(68° - 77° F)

Each tablet contains
Clindamycin hydrochloride
equivalent to clindamycin, 75 mg.

Mfd for DELMARVA LABORATORIES, INC.
Middleton, VA 22113
By DIAMOND ANIMAL HEALTH, INC.
Des Moines, IA 50327

NDC 59079-402-10
200 Tablets

CLINTABS®

Tablets
clindamycin hydrochloride

75 mg

Equi to 75 mg clindamycin

For Use In Animals Only

Caution: Federal (USA) law restricts this drug to
use by or on the order of a licensed veterinarian.

ANADA # 200-316, Approved by FDA



01850

Approved for use in canines
Recommended dosage:
For therapy of wounds,
abscesses and dental infections,
1 tablet for each 30 pounds
body weight every 12 hours.

For therapy of osteomyelitis,
1 tablet for each 15 pounds
body weight every 12 hours.

See package insert for complete
product information.

Warning - Not for human use
Keep container tightly closed

Store at controlled room
temperature 20°-25° C
(68° - 77° F)

Each tablet contains
Clindamycin hydrochloride
equivalent to clindamycin, 75 mg.

Mfd for DELMARVA LABORATORIES, INC.
Middleton, VA 22113
By DIAMOND ANIMAL HEALTH, INC.
Des Moines, IA 50327

NDC 59079-402-10
200 Tablets

CLINTABS®

Tablets
clindamycin hydrochloride

75 mg

Equi to 75 mg clindamycin

For Use In Animals Only

Caution: Federal (USA) law restricts this drug to
use by or on the order of a licensed veterinarian.

ANADA # 200-316, Approved by FDA



01850

Approved for use in canines
Recommended dosage:
For therapy of wounds,
abscesses and dental infections,
1 tablet for each 30 pounds
body weight every 12 hours.

For therapy of osteomyelitis,
1 tablet for each 15 pounds
body weight every 12 hours.

See package insert for complete
product information.

Warning - Not for human use
Keep container tightly closed

Store at controlled room
temperature 20°-25° C
(68° - 77° F)

Each tablet contains
Clindamycin hydrochloride
equivalent to clindamycin, 75 mg.

Mfd for DELMARVA LABORATORIES, INC.
Middleton, VA 22113
By DIAMOND ANIMAL HEALTH, INC.
Des Moines, IA 50327

NDC 59079-402-10
200 Tablets

CLINTABS®

Tablets
clindamycin hydrochloride

75 mg

Equi to 75 mg clindamycin

For Use In Animals Only

Caution: Federal (USA) law restricts this drug to
use by or on the order of a licensed veterinarian.

ANADA # 200-316, Approved by FDA



01850

Approved for use in canines
Recommended dosage:
For therapy of wounds,
abscesses and dental infections,
1 tablet for each 60 pounds
body weight every 12 hours.
For therapy of osteomyelitis,
1 tablet for each 30 pounds
body weight every 12 hours.
See package insert for complete
product information.
Warning - Not for human use
Keep container tightly closed
Store at controlled room
temperature 20°-25° C
(68° - 77° F)
Each tablet contains
Clindamycin hydrochloride
equivalent to clindamycin, 150 mg

Mfd for: DELMARVA LABORATORIES, INC.
Middletown, VA 23113
By: DIAMOND ANIMAL HEALTH, INC.
Des Moines, IA 50327

NDC 59079-404-09
100 Tablets

CLINTABS®

Tablets
clindamycin hydrochloride

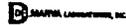
150 mg

Equivalent to 150 mg clindamycin

For Use In Animals Only

Caution: Federal (USA) law restricts this drug to
use by or on the order of a licensed veterinarian

ANADA # 200 316, Approved by FDA



01851

Approved for use in canines
Recommended dosage:
For therapy of wounds,
abscesses and dental infections,
1 tablet for each 60 pounds
body weight every 12 hours.
For therapy of osteomyelitis,
1 tablet for each 30 pounds
body weight every 12 hours.
See package insert for complete
product information.
Warning - Not for human use
Keep container tightly closed
Store at controlled room
temperature 20°-25° C
(68° - 77° F)
Each tablet contains
Clindamycin hydrochloride
equivalent to clindamycin, 150 mg

Mfd for: DELMARVA LABORATORIES, INC.
Middletown, VA 23113
By: DIAMOND ANIMAL HEALTH, INC.
Des Moines, IA 50327

NDC 59079-404-09
100 Tablets

CLINTABS®

Tablets
clindamycin hydrochloride

150 mg

Equivalent to 150 mg clindamycin

For Use In Animals Only

Caution: Federal (USA) law restricts this drug to
use by or on the order of a licensed veterinarian

ANADA # 200 316 Approved by FDA



01851

Approved for use in canines.
Recommended dosage:
For therapy of wounds,
abscesses and dental infections,
1 tablet for each 60 pounds
body weight every 12 hours.
For therapy of osteomyelitis,
1 tablet for each 30 pounds
body weight every 12 hours.
See package insert for complete
product information.
Warning - Not for human use
Keep container tightly closed
Store at controlled room
temperature 20°-25° C
(68° - 77° F)
Each tablet contains
Clindamycin hydrochloride
equivalent to clindamycin, 150 mg

Mfd for: DELMARVA LABORATORIES, INC.
Middletown, VA 23113
By: DIAMOND ANIMAL HEALTH, INC.
Des Moines, IA 50327

NDC 59079-404-09
100 Tablets

CLINTABS®

Tablets
clindamycin hydrochloride

150 mg

Equivalent to 150 mg clindamycin

For Use In Animals Only

Caution: Federal (USA) law restricts this drug to
use by or on the order of a licensed veterinarian

ANADA # 200 316, Approved by FDA



01851