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# CLINTABS® TABLETS

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Virbac

**brand of clindamycin hydrochloride tablets**

**ANADA # 200-316, Approved by FDA**

## DESCRIPTION

Clintabs (clindamycin hydrochloride) Tablets contain clindamycin hydrochloride which is the hydrated salt of clindamycin. Clindamycin is a semisynthetic antibiotic produced by a 7(S)-chlorosubstitution of the 7(R)-hydroxyl group of a naturally produced antibiotic produced by *Streptomyces lincolnensis var. lincolnensis*.

**Clintabs Tablets:**

**25 mg Tablet**, each white tablet is marked "C 25" on one side and contains clindamycin hydrochloride equivalent to 25 mg of clindamycin.

**75 mg Tablet**, each white tablet is marked "C 75" on one side and contains clindamycin hydrochloride equivalent to 75 mg of clindamycin.

**150 mg Tablet**, each white tablet is marked "C150" on one side and contains clindamycin hydrochloride equivalent to 150 mg of clindamycin.

## ACTIONS

**Site and Mode of Action:** Clindamycin is an inhibitor of protein synthesis in the bacterial cell. The site of binding appears to be in the 5OS sub-unit of the ribosome. Binding occurs to the soluble RNA fraction of certain ribosomes, thereby inhibiting the binding of amino acids to those ribosomes. Clindamycin differs from

cell wall inhibitors in that it causes irreversible modification of the protein-synthesizing subcellular elements at the ribosomal level.

**Microbiology:** The following clindamycin *in vitro* data are available but their clinical significance is unknown. Clindamycin has been shown to have *in vitro* activity against canine isolates of the following organisms:

*Aerobic gram positive cocci,* including: *Staphylococcus aureus* (penicillinase and non-penicillinase producing strains)*, Staphylococcus epidermidis, Streptococci* (except *S. faecalis).*

*Anaerobic gram negative bacilli,* including: *Bacteroides species, Fusobacterium species.*

*Anaerobic gram positive nonsporeforming bacilli,* including: *Propionibacterium, Eubacterium, Actinomyces species.*

*Anaerobic and microaerophilic gram positive cocci,* including: *Peptococcus species, Peptostreptococcus species, Microaerophilic streptococci.*

*Clostridia:* Most *C. perfringens* are susceptible, but other species may be resistant to clindamycin.

OVERALL SUSCEPTIBILITY TO CLINDAMYCIN OF ANAEROBES ISOLATED FROM CANINE LESIONS. DATA OBTAINED FROM THREE VETERINARY DIAGNOSTIC LABORATORIES:

| | Susceptible ≤3.2 µg/mL | Resistant ≥4.0 µg/mL |
|---|---|---|
| All Isolates | 122/137 (89%) | 15/137 (11%) |
| *Clostridium spp.* | 41/49 (84%) | 8/49 (16%) |
| *Bacteroides spp.* | 42/46 (91%) | 4/46 (9%) |
| *Fusobacterium spp.* | 16/16 (100%) | 0/16 (0%) |
| *Peptostreptococcus spp.* | 15/16 (94%) | 1/16 (6%) |
| *Actinomyces spp.* | 5/6 (83%) | 1/6 (17%) |
| *Proprionibacterium spp.* | 3/4 (75%) | 1/4 (25%) |

*Mycoplasma species:* Most mycoplasma species are susceptible to clindamycin.

Clindamycin and erythromycin show parallel resistance. Partial cross resistance has been demonstrated between clindamycin, erythromycin and macrolide antibiotics.

## PHARMACOLOGY

**Absorption:** Clindamycin hydrochloride is rapidly absorbed from the canine gastrointestinal tract. Dogs orally dosed with therapeutic amounts of clindamycin hydrochloride demonstrated antibacterial serum levels of the drug within 15 minutes post-dosing.

**Canine Serum Levels:** Therapeutically effective serum levels of clindamycin hydrochloride can be maintained by oral dosing at the rate of 2.5 mg/lb every 12 hours. Dogs orally dosed with clindamycin hydrochloride at 2.5 mg/lb every 12 hours during a 72 hours dosing regimen continuously maintained antibacterial serum levels of the drug. This same study revealed that average peak serum concentrations occurred 1 hour and 15 minutes after

dosing. The biological half-life for clindamycin hydrochloride in dog serum was about 5 hours. There was no bioactivity accumulation after a regimen of multiple oral doses.

## METABOLISM AND EXCRETION

Extensive studies of the metabolism and excretion of clindamycin hydrochloride administered orally in animals and humans have shown that unchanged drug and bioactive and bioinactive metabolites are excreted in urine and feces. Almost all of the bioactivity detected in serum after clindamycin hydrochloride product administration is due to the parent molecule (clindamycin). Urine bioactivity, however, reflects a mixture of clindamycin and active metabolites, especially N-demethyl clindamycin and clindamycin sulfoxide.

## TOXICOLOGY AND SAFETY

One year oral toxicity studies in rats and dogs at doses of 30, 100, and 300 mg/kg/day have shown clindamycin hydrochloride to be well tolerated. Differences did not occur in the parameters evaluated to assess toxicity when comparing groups of treated animals with contemporary controls. Rats administered clindamycin hydrochloride at 600 mg/kg/day for six months tolerated the drug well; however, dogs orally dosed at 600 mg/kg/day vomited, had anorexia, and subsequently lost weight.

Safety in gestating bitches or breeding males has not been established.

## INDICATIONS

**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.* (See Microbiology section for additional information.)

## IN VITRO SUSCEPTIBILITY TESTING

Susceptibility tests should be done on samples collected prior to initiation of therapy with Clintabs (clindamycin hydrochloride) Tablets. Clindamycin susceptibility testing is performed by using CLEOCIN® Susceptibility Disks (clindamycin 2 mcg) and CLEOCIN® Susceptibility Powder 20 mg. A standardized disk testing procedure* is recommended for determining susceptibility of aerobic bacteria to clindamycin. A description is contained in the CLEOCIN® Susceptibility Disk insert. Using this method, the laboratory can designate isolates as resistant, intermediate, or susceptible. Tube or agar dilution methods may be used for aerobic and anaerobic bacteria. When the directions in the CLEOCIN® Susceptibility Powder insert are followed, a MIC (minimal inhibitory concentration) of 1.6 mcg/mL may be considered susceptible; MICs of 1.6 to 4.8 mcg/mL may be considered intermediate and MICs greater than 4.8 mcg/mL may be considered resistant.

* Bauer, AW; Kirby, WM; Sherris, JC; Turck, M: Antibiotic susceptibility testing by a standardized single disk method, *Am. J. Clin.Path.,* 45: 493-496, 1966. Standardized Disk Susceptibility Test, *Federal Register,* 37: 20527-29, 1972.

## CONTRAINDICATIONS

Clintabs (clindamycin hydrochloride) Tablets are contraindicated in animals with a history of hypersensitivity to preparations containing clindamycin or lincomycin.

Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas or ruminating animals.

## WARNINGS

Not for human use.

## PRECAUTIONS

Clintabs (clindamycin hydrochloride) Tablets should be prescribed with caution in atopic animals.

During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed.

The use of clindamycin hydrochloride occasionally results in overgrowth of non-susceptible organisms such as clostridia and yeasts. Therefore, the administration of clindamycin hydrochloride should be avoided in those species sensitive to the gastrointestinal effects of clindamycin (see CONTRAINDICATIONS). Should superinfections occur, appropriate measures should be taken as indicated by the the clinical situation.

Patients with very severe renal disease and/or very severe hepatic disease accompanied by severe metabolic aberrations should be dosed with caution, and serum clindamycin levels monitored during high-dose therapy.

Clindamycin hydrochloride has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, clindamycin hydrochloride should be used with caution in animals receiving such agents.

Safety in gestating bitches or breeding males has not been established.

## SIDE EFFECTS

Side effects occasionally observed in either clinical trials or during clinical use were vomiting and diarrhea.

## DOSAGE AND ADMINISTRATION

### Canine Infected Wounds, Abscesses and Dental Infections

**Oral:** 2.5 mg/lb body weight every 12 hours. **Duration:** Treatment with clindamycin hydrochloride products 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:

### Tablets

**Clintabs 25 mg,** administer 1 tablet every 12 hours for each 10 pounds of body weight.

**Clintabs 75 mg,** administer 1 tablet every 12 hours for each 30 pounds of body weight.

**Clintabs 150 mg,** administer 1 tablet every 12 hours for each 60 pounds of body weight.

**Canine Osteomyelitis**

**Oral:** 5.0 mg/lb body weight every 12 hours. **Duration:** Treatment with Clintabs (clindamycin hydrochloride) Tablets 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:**

**Tablets**

**Clintabs 25 mg,** administer 1 tablet every 12 hours for each 5 pounds of body weight.

**Clintabs 75 mg,** administer 1 tablet every 12 hours for each 15 pounds of body weight.

**Clintabs 150 mg,** administer 1 tablet every 12 hours for each 30 pounds of body weight.

**HOW SUPPLIED**

Clintabs Tablets are available as:

25 mg tablets supplied in bottles of 600

75 mg tablets supplied in bottles of 200

150 mg tablets supplied in bottles of 100

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

Keep container tightly closed.

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

**For Use In Animals Only**

**Manufactured for: Virbac AH, Inc., P.O. Box 162059, Fort Worth, TX 76161**

**(800) 338-3659**



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| | | NDC | Product Code | |
|---|---|---|---|---|
| 25 mg | 600 Tablets | 051311-400-25 | 902560 | 01849 |
| 75 mg | 200 Tablets | 051311-402-75 | 907520 | 01850 |
| 150 mg | 100 Tablets | 051311-404-15 | 915010 | 01851 |

**NAC No.:** 10230860