

CLINTABS- clindamycin hydrochloride tablet
Virbac AH, Inc.

Clintabs® Tablets

brand of clindamycin hydrochloride tablets, USP

DESCRIPTION

Clintabs 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 (For Use in Dogs Only)

25 mg Tablet, each white bisected tablet is marked "C" above the bisect and "25" below the bisect and contains clindamycin hydrochloride equivalent to 25 mg of clindamycin.

75 mg Tablet, each white bisected tablet is marked "C" above the bisect and "75" below the bisect and contains clindamycin hydrochloride equivalent to 75 mg of clindamycin.

150 mg Tablet, each white tablet is marked "C 150" 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 50S 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

Clindamycin is a lincosaminide antimicrobial agent with activity against a wide variety of aerobic and anaerobic bacterial pathogens. Clindamycin is a bacteriostatic compound that inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit. The minimum inhibitory concentrations (MICs) of Gram-positive and obligate anaerobic pathogens isolated from dogs in the United States are presented in Table 1. Bacteria were isolated in 1998-1999. All MICs were performed in accordance with the National Committee for Clinical Laboratory Standards (NCCLS).

Table 1. Clindamycin MIC Values ($\mu\text{g}/\text{mL}$) from Diagnostic Laboratory Survey Data Evaluating Canine Pathogens in the U.S. during 1998-99*

| Organism | Number of Isolates | MIC₅₀ | MIC₈₅ | MIC₉₀ | Range |
|-----------------------------------|---------------------------|-------------------------|-------------------------|-------------------------|-------------------|
| Soft Tissue/Wound [†] | | | | | |
| <i>Staphylococcus aureus</i> | 17 | 0.5 | 0.5 | ≥ 4.0 | 0.25- ≥ 4.0 |
| <i>Staphylococcus intermedius</i> | 28 | 0.25 | 0.5 | ≥ 4.0 | 0.125- ≥ 4.0 |
| <i>Staphylococcus</i> spp. | 18 | 0.5 | 0.5 | ≥ 4.0 | .025- ≥ 4.0 |
| Beta-hemolytic streptococci | 46 | 0.5 | 0.5 | ≥ 4.0 | 0.25- ≥ 4.0 |
| <i>Streptococcus</i> spp. | 11 | 0.5 | ≥ 4.0 | ≥ 4.0 | 0.25- ≥ 4.0 |
| Osteomyelitis/Bone [‡] | | | | | |

| | | | | | |
|-----------------------------------|----|------|------|------|------------------|
| <i>Staphylococcus aureus</i> | 20 | 0.5 | 0.5 | 0.5 | 0.5 [§] |
| <i>Staphylococcus intermedius</i> | 15 | 0.5 | ≥4.0 | ≥4.0 | 0.25-≥4.0 |
| <i>Staphylococcus</i> spp. | 18 | 0.5 | ≥4.0 | ≥4.0 | 0.25-≥4.0 |
| Beta-hemolytic streptococci | 21 | 0.5 | 2.0 | 2.0 | 0.25-≥4.0 |
| <i>Streptococcus</i> spp. | 21 | ≥4.0 | ≥4.0 | ≥4.0 | 0.25-≥4.0 |
| Dermal/Skin[¶] | | | | | |
| <i>Staphylococcus aureus</i> | 25 | 0.5 | ≥4.0 | ≥4.0 | 0.25-≥4.0 |
| <i>Staphylococcus intermedius</i> | 48 | 0.5 | ≥4.0 | ≥4.0 | 0.125-≥4.0 |
| <i>Staphylococcus</i> spp. | 32 | 0.5 | ≥4.0 | ≥4.0 | 0.25-≥4.0 |
| Beta-hemolytic streptococci | 17 | 0.5 | 0.5 | 0.5 | 0.25-0.5 |

* The correlation between the *in vitro* susceptibility data and clinical response has not been determined.

† Soft Tissue/Wound: includes samples labeled wound, abscess, aspirate, exudates, draining tract, lesion, and mass

‡ Osteomyelitis/Bone: includes samples labeled bone, fracture, joint, tendon

§ No range, all isolates yielded the same value

¶ Dermal/Skin: includes samples labeled skin, skin swab, biopsy, incision, lip

PHARMACOLOGY

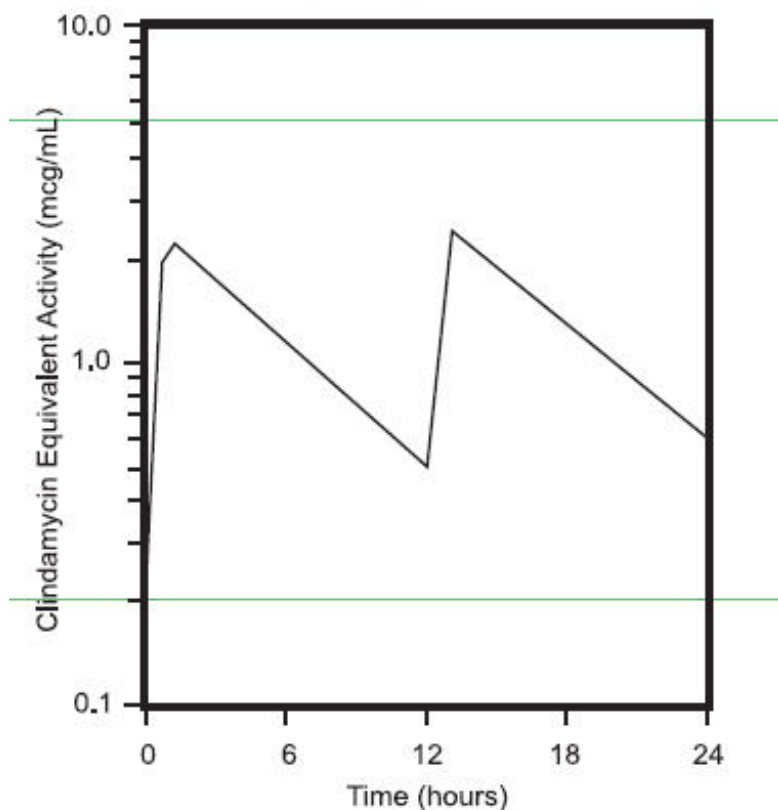
Absorption

Clindamycin hydrochloride is rapidly absorbed from the canine gastrointestinal tract.

Dog Serum Levels

Serum levels at or above 0.5 µg/mL can be maintained by oral dosing at a rate of 2.5 mg/lb of clindamycin hydrochloride every 12 hours. This same study revealed that average peak serum concentrations of clindamycin occur 1 hour and 15 minutes after oral dosing. The elimination half-life for clindamycin in dog serum was approximately 5 hours. There was no bioactivity accumulation after a regimen of multiple oral doses in healthy dogs.

Clindamycin Serum Concentrations 2.5 mg/lb (5.5 mg/kg) After B.I.D. Oral Dose of Clindamycin Hydrochloride to Dogs



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 administration is due to the parent molecule (clindamycin). Urine bioactivity, however, reflects a mixture of clindamycin and active metabolites, especially N-dimethyl clindamycin and clindamycin sulfoxide.

ANIMAL SAFETY SUMMARY

Rat and Dog Data

One year oral toxicity studies in rats and dogs at doses of 30, 100 and 300 mg/kg/day (13.6, 45.5 and 136.4 mg/lb/day) have shown clindamycin hydrochloride capsules 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 (272.7 mg/lb/day) for six months tolerated the drug well; however, dogs orally dosed at 600 mg/kg/day (272.7 mg/lb/day) vomited, had anorexia, and subsequently lost weight. At necropsy these dogs had erosive gastritis and focal areas of necrosis of the mucosa of the gallbladder.

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

INDICATIONS

Clintabs (brand of clindamycin hydrochloride) Tablets (for use in dogs only) 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 melaninogenica*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

Dental infections due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenica*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

Osteomyelitis due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenica*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

CONTRAINDICATIONS

Clintabs 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

Keep out of reach of children. Not for human use.

PRECAUTIONS

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 Clintabs Tablets 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 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, Clintabs Tablets should be used with caution in animals receiving such agents.

Safety in gestating bitches or breeding male dogs has not been established.

ADVERSE REACTIONS

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

To report adverse reactions or a suspected adverse reaction, call 1-800-338-3659.

DOSAGE AND ADMINISTRATION

Dogs

Infected Wounds, Abscesses, and Dental Infections

Oral

2.5-15.0 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 1-6 tablets every 12 hours for each 10 pounds of body weight.

Clintabs 75 mg, administer 1-6 tablets every 12 hours for each 30 pounds of body weight.

Clintabs 150 mg, administer 1-6 tablets every 12 hours for each 60 pounds of body weight.

Dogs

Osteomyelitis

Oral

5.0-15.0 mg/lb body weight every 12 hours.

Duration

Treatment with clindamycin hydrochloride 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 2-6 tablets every 12 hours for each 10 pounds of body weight.

Clintabs 75 mg, administer 2-6 tablets every 12 hour for each 30 pounds of body weight.

Clintabs 150 mg, administer 2-6 tablets every 12 hours for each 60 pounds of body weight.

HOW SUPPLIED

Clintabs Tablets are available as:

25 mg - bottles of 100
75 mg - bottles of 100
150 mg - bottles of 100

ANADA #200-316, Approved by FDA

To report a suspected adverse reaction or to request a material safety data sheet (MSDS), call 1-800-338-3659.

Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].

Caution

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

Mfd. for
Virbac AH, Inc.
Fort Worth, TX 76137-4611, USA

Revised December 08
301617-04

Clintabs is a registered trademark of Virbac AH, Inc.

PRINCIPAL DISPLAY PANEL - 25 mg/400 Tablet Bottle Label

NDC-051311-400-40

Virbac
ANIMAL HEALTH

Clintabs[®] Tablets
clindamycin hydrochloride
25 mg tablets, USP

Equiv. to **25 mg** clindamycin

For Use in Dogs 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

400 Tablets

Approved for use in dogs.

Recommended dosage:

For therapy of wounds, abscesses and dental infections, 1-6 tablets for each 10 pounds of body weight every 12 hours.

For therapy of osteomyelitis, 2-6 tablets for each 10 pounds body weight every 12 hours.

See package insert for complete product information.

Warning – Keep out of reach of children.

Not for human use.

Keep container tightly closed.

Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].

Each tablet contains:

Clindamycin hydrochloride equivalent to clindamycin, 25 mg.

Mfd. for: **Virbac AH, Inc.** · P.O. Box 162059
Fort Worth, TX 76161 · (800) 338-3659 301675-02

NDC-051311-400-40



Clintabs® Tablets
clindamycin hydrochloride
25 mg tablets, USP

Equiv. to 25 mg clindamycin

For Use in Dogs 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

400 Tablets



PRINCIPAL DISPLAY PANEL - 75 mg/200 Tablet Bottle Label

NDC-051311-402-75

Virbac

ANIMAL HEALTH

Clintabs® Tablets
clindamycin hydrochloride
75 mg tablets, USP

Equiv. to 75 mg clindamycin

For Use in Dogs 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

200 Tablets

Approved for use in dogs.

Recommended dosage:

For therapy of wounds, abscesses and dental infections, 1-6 tablets for each 30 pounds of body weight every 12 hours.

For therapy of osteomyelitis, 2-6 tablets for each 30 pounds body weight every 12 hours.

See package insert for complete product information.

Warning – Keep out of reach of children.

Not for human use.

Keep container tightly closed.

Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].

Each tablet contains:

Clindamycin hydrochloride equivalent to clindamycin, 75 mg.

Mfd. for: **Virbac AH, Inc.** · P.O. Box 162059
Fort Worth, TX 76161 · (800) 338-3659 301613-02

NDC-051311-402-75



Clintabs® Tablets
clindamycin hydrochloride
75 mg tablets, USP

Equiv. to 75 mg clindamycin

For Use in Dogs 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

200 Tablets



PRINCIPAL DISPLAY PANEL - 150 mg/100 Tablet Bottle Label

NDC-051311-404-15

Virbac

ANIMAL HEALTH

Clintabs® Tablets
clindamycin hydrochloride
150 mg tablets, USP

Equiv. to 150 mg clindamycin

For Use in Dogs 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

100 Tablets

Approved for use in dogs.

Recommended dosage:

For therapy of wounds, abscesses and dental infections, 1-6 tablets for each 60 pounds of body weight every 12 hours.

For therapy of osteomyelitis, 2-6 tablets for each 60 pounds body weight every 12 hours.

See package insert for complete product information.

Warning – Keep out of reach of children.

Not for human use.

Keep container tightly closed.

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].

Each tablet contains:

Clindamycin hydrochloride equivalent to clindamycin, 150 mg.

Mfd. for: Virbac AH, Inc. · P.O. Box 162059
Fort Worth, TX 76161 · (800) 338-3659 301614-02

NDC-051311-404-15

Virbac
ANIMAL HEALTH

Clintabs® Tablets
clindamycin hydrochloride
150 mg tablets, USP

Equiv. to 150 mg clindamycin

For Use in Dogs 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

100 Tablets



CLINTABS

clindamycin hydrochloride tablet

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|---------------|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:51311-400 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| clindamycin hydrochloride (UNII: T20OQ1YN1W) (clindamycin - UNII:3U02EL437C) | clindamycin | 25 mg |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | WHITE | Score | 2 pieces |
| Shape | ROUND | Size | 6mm |
| Flavor | | Imprint Code | C25 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:51311-400-40 | 400 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANADA | ANADA200316 | 01/26/2010 | |

CLINTABS

clindamycin hydrochloride tablet

Product Information

| | | | |
|-------------------------|--------------------------|--------------------|---------------|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:51311-402 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| clindamycin hydrochloride (UNII: T20OQ1YN1W) (clindamycin - UNII:3U02EL437C) | clindamycin | 75 mg |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | WHITE | Score | 2 pieces |
| Shape | ROUND | Size | 8mm |
| Flavor | | Imprint Code | C75 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:51311-402-75 | 200 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANADA | ANADA200316 | 01/26/2010 | |

CLINTABS

clindamycin hydrochloride tablet

Product Information

| | | | |
|-------------------------|--------------------------|--------------------|---------------|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:51311-404 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| clindamycin hydrochloride (UNII: T20OQ1YN1W) (clindamycin - UNII:3U02EL437C) | clindamycin | 150 mg |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | C150 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:51311-404-15 | 100 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANADA | ANADA200316 | 01/26/2010 | |

Labeler - Virbac AH, Inc. (131568396)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|---------------------|
| Virbac Corporation | | 829166276 | MANUFACTURE |

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|---------------------|
| Chongqing Carelife Pharmaceutical Co. LTD | | 531132009 | api manufacture |