

**CLINTABS- clindamycin hydrochloride tablet**  
**Virbac AH, Inc.**

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**CLINTABS®**  
**(clindamycin hydrochloride tablets)**

**CAUTION:**

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

**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.

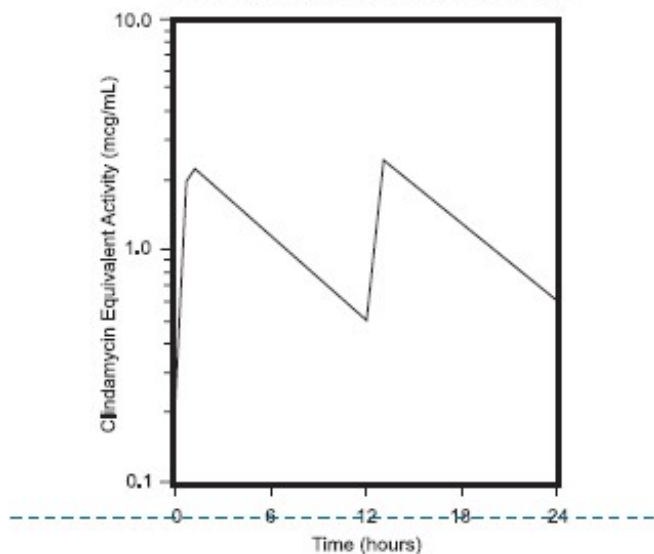
**150 mg Tablet**, each white tablet is marked "C 150" on one side and contains clindamycin hydrochloride equivalent to 150 mg of clindamycin.

**CLINICAL 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.

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-demethyl clindamycin and clindamycin sulfoxide.

**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 sub-unit. 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 Clinical and Laboratory Standards Institute (CLSI).

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

Organism	Number of Isolates	MIC <sub>50</sub>	MIC <sub>85</sub>	MIC <sub>90</sub>	Range
<b>Soft Tissue/Wound<sup>2</sup></b>					
<i>Staphylococcus aureus</i>	17	0.5	0.5	$\geq 4.0$	0.25- $\geq 4.0$
<i>Staphylococcus intermedius</i>	28	0.25	0.5	$\geq 4.0$	0.125- $\geq 4.0$
<i>Staphylococcus</i> spp.	18	0.5	0.5	$\geq 4.0$	0.25- $\geq 4.0$
Beta-hemolytic streptococci	46	0.5	0.5	$\geq 4.0$	0.25- $\geq 4.0$
<i>Streptococcus</i> spp.	11	0.5	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
<b>Osteomyelitis/Bone<sup>3</sup></b>					
<i>Staphylococcus aureus</i>	20	0.5	0.5	0.5	0.5 <sup>4</sup>
<i>Staphylococcus intermedius</i>	15	0.5	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
<i>Staphylococcus</i> spp.	18	0.5	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
Beta-hemolytic streptococci	21	0.5	2.0	2.0	0.25- $\geq 4.0$
<i>Streptococcus</i> spp.	21	$\geq 4.0$	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
<b>Dermal/Skin<sup>5</sup></b>					
<i>Staphylococcus aureus</i>	25	0.5	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
<i>Staphylococcus intermedius</i>	48	0.5	$\geq 4.0$	$\geq 4.0$	0.125- $\geq 4.0$
<i>Staphylococcus</i> spp.	32	0.5	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
Beta-hemolytic streptococci	17	0.5	0.5	0.5	0.25-0.5

<sup>1</sup> The correlation between the *in vitro* susceptibility data and clinical response has not been determined.

<sup>2</sup> Soft Tissue/Wound: includes samples labeled wound, abscess, aspirate, exudates, draining tract, lesion, and mass

<sup>3</sup> Osteomyelitis/Bone: includes samples labeled bone, fracture, joint, tendon

<sup>4</sup> No range, all isolates yielded the same value

<sup>5</sup> Dermal/Skin: includes samples labeled skin, skin swab, biopsy, incision, lip

## INDICATIONS

CLINTABS® (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 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*.

## **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.

Keep CLINTABS tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

## **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 hours for each 30 pounds of body weight.

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

## 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 gall bladder.

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

## STORAGE

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

## HOW SUPPLIED

CLINTABS tablets are available as:

25 mg - bottles of 400

75 mg - bottles of 200

150 mg - bottles of 100

Approved by FDA under ANADA # 200-316

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Virbac AH, Inc. at 1-800-338-3659 or [us.virbac.com](http://us.virbac.com). For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

Manufactured for: Virbac AH, Inc.  
P.O. Box 162059  
Fort Worth, TX 76161, USA  
1-800-338-3659

Revised: February 2023 301617-06  
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## CLINTABS 25 mg



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 CLINTABS tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.  
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.  
Manufactured for: Virbac AH, Inc. Fort Worth, TX 76161  
1-800-338-3659 301675-03



**CLINTABS<sup>®</sup>**  
(clindamycin hydrochloride tablets)  
**25 mg**  
Equiv. to 25 mg clindamycin  
**For Use in Dogs Only**  
**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
Approved by FDA under ANADA # 200-316 **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 CLINTABS tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.  
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.  
Manufactured for: Virbac AH, Inc. Fort Worth, TX 76161  
1-800-338-3659 301675-03



**CLINTABS<sup>®</sup>**  
(clindamycin hydrochloride tablets)  
**25 mg**  
Equiv. to 25 mg clindamycin  
**For Use in Dogs Only**  
**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
Approved by FDA under ANADA # 200-316 **400 Tablets**





# CLINTABS 75 mg

8 14514 02328 4

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 CLINTABS tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.  
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.  
Manufactured for: **Virbac AH, Inc.** Fort Worth, TX 76161  
1-800-338-3659 301613-03

8 14514 02328 4

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 CLINTABS tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.  
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.  
Manufactured for: **Virbac AH, Inc.** Fort Worth, TX 76161  
1-800-338-3659 301613-03

**Virbac**

**CLINTABS®**  
(clindamycin hydrochloride tablets)  
**75 mg**  
Equiv. to 75 mg clindamycin  
**For Use in Dogs Only**  
**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
Approved by FDA under ANADA # 200-316 **200 Tablets**

**Virbac**

**CLINTABS®**  
(clindamycin hydrochloride tablets)  
**75 mg**  
Equiv. to 75 mg clindamycin  
**For Use in Dogs Only**  
**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
Approved by FDA under ANADA # 200-316 **200 Tablets**

# CLINTABS 150 mg

8 14514 02344 4

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 CLINTABS tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.  
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.  
Manufactured for: **Virbac AH, Inc.** Fort Worth, TX 76161  
1-800-338-3659 301614-03

8 14514 02344 4

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 CLINTABS tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.  
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.  
Manufactured for: **Virbac AH, Inc.** Fort Worth, TX 76161  
1-800-338-3659 301614-03

**Virbac**

**CLINTABS®**  
(clindamycin hydrochloride tablets)  
**150 mg**  
Equiv. to 150 mg clindamycin  
**For Use in Dogs Only**  
**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
Approved by FDA under ANADA # 200-316 **100 Tablets**

**Virbac**

**CLINTABS®**  
(clindamycin hydrochloride tablets)  
**150 mg**  
Equiv. to 150 mg clindamycin  
**For Use in Dogs Only**  
**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
Approved by FDA under ANADA # 200-316 **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: T200Q1YN1W) (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, analysis, label

## Establishment

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

## Establishment

Name	Address	ID/FEI	Business Operations
Particle Technology Labs		808076947	analysis

Revised: 6/2023

Virbac AH, Inc.